CA-MI

Italian Medical Touch

SURGICAL SUCTION UNITS

CATALOGUE 2021

COMPANY PROFILE

Located nearby Parma, in the North of Italy, CA-MI is an Italian family-run factory founded in the early 80's and committed in the production of electromedical equipments, namely SURGICAL SUCTION UNITS for the aspiration of human and animal fluids, used by home-care, hospital, emergency, veterinary and aesthetic professionals. With presence in over 90 countries, and listed in international organizations such as UN, UNICEF, UNFPA, CA-MI offers a comprehensive line to meet the various requirements, including a variety of designs from compact tabletop (ASKIR's), to portable with battery back-up (BR's), to professional units on castors (HOSPIVAC's). Characterized by a great versatility of applications with easy interchange of accessories, all CA-MI suction pumps are manufactured in Italy with flame retardant PC/ABS in compliance with the latest normatives and constitute a solid support whenever electric suction is required. Special attention is paid to liquid collecting jars to offer operators all options. Whether reusable or disposable, different materials and sizes are available, and can be easily replaced with the new Multi Purpose Rail system. CA-MI suction pumps are indicated for use in various specialities, finding applications in OT, ICU, General Surgery, Gastroenterology, Obstetrics, Endoscopy, ENT, Liposuction, Patient Transfer, Rescue, Ambulance Car, Veterinary, Dentistry, just to mention a few.

CA-MI is also addressing to medical and pharmacy retailers with a vast line of medical devices for home use and is one of the most preferred partners in the marketplace for OEM-basis supplies. Visitors are welcome to meet the members of the CA-MI Export Team on occasion of the major international exhibitions such as Medica in Dusseldorf (D) or Arab Health in Dubai (UAE), where we are costantly present with our entire range of medical devices.

QUALITY

Relying on in-house R&D and design departments, all CA-MI suction devices are manufactured in Italy using state-of-the-art and wear resistant materials, in compliance with: UNI EN ISO 9001:2015 and EN ISO 13485:2016 normatives and carry relevant CE 0123 number certified by German Notified Body TÜV SÜD Product Service GmbH.

CLASSIFICATIONS (MDD 93/42/EEC and subsequent changes)
Class IIa Medical Devices
All Suction Units
Class Im with function of measure
Flovac Liners and Containers

INDEX

SURGICAL SUCTION UNITS

INTRODUCTION

Intended Use

Electric suction units are medical devices used in wards, theaters, ambulances, home-care and other fields for aspirating human or animal fluids from the mouth, the airways and from operation sites by sucking the material through a cannula into a collection jar. Mobile electric suction units offer a convenient alternative to central vacuum systems.

CA-MI suction units are divided into 3 main categories:

DESK-TYPE

Portable suction units with reduced size and weight that can be easily displaced. Trolley on castors available as an option.

BATTERY-OPERATED

Suction units that besides standard operation by mains have autonomy by internal rechargeable battery.

ON CASTORS

Professional suction units on antistatic castors, offering a great choice of accessories for various applications.

Fields of application

CA-MI suction units find application in a variety of different fields, such as ENT, Tracheostomy, Endoscopy, Gastroenterology, General Surgery, Obstetrics, Veterinary, Dental, Emergency, Crash Carts, Ambulance and many others.

Configurations

All CA-MI suction units are all provided with a number of standard accessories, along with optional accessories to facilitate the operation of medical staff, professionals and lay people.

- Vacuum pump
- Vacuum regulator footswitch
- Jar for liquid collection with overflow valve to prevent liquid from going into the pump
- Hydrophobic/bacterial filter to avoid contaminations and liquid passage
- Vacuum regulator and gauge
- Suction tubes
- Wall mount for ambulances

A number of optional accessories / functions is also available

- Foot-pedal switch with double-mode operation
- Change-over function to quickly switch suction from one jar to the next
- Antistatic castors with brakes and 360° swivel for easy displacement
- Built-in rechargeable battery for operation without mains

FIELDS OF APPLICATION

ENVIRONMENT	ENVIRONMENT	ENVIRONMENT
Home Care	Emergency Rescue Mobility	Operating Theatre Professionals Aesthetics
SALES CHANNELS	**SALES CHANNELS**	**SALES CHANNELS**
Home Care Providers Medical Shops Specialized Retailers	Governmental Tenders Ambulance Makers Red Cross and similar	Governmental Tenders Hospital Supplies Aesthetics Surgeons
PRODUCTS	**PRODUCTS**	**PRODUCTS**
Aspiret Askir 20 Askir 30 Askir 230/12V BR Askir 36 BR Askir 36 Li-Ion	Askir 230/12V BR Askir 36 BR | Askir 36 Li-Ion Askir 118 | Askir 118 Basic Askir 30 12V Emivac Askir C30 BR Hospivac BR	Askir C30 Hospivac 350 Hospivac 400

MAIN CHARACTERISTICS

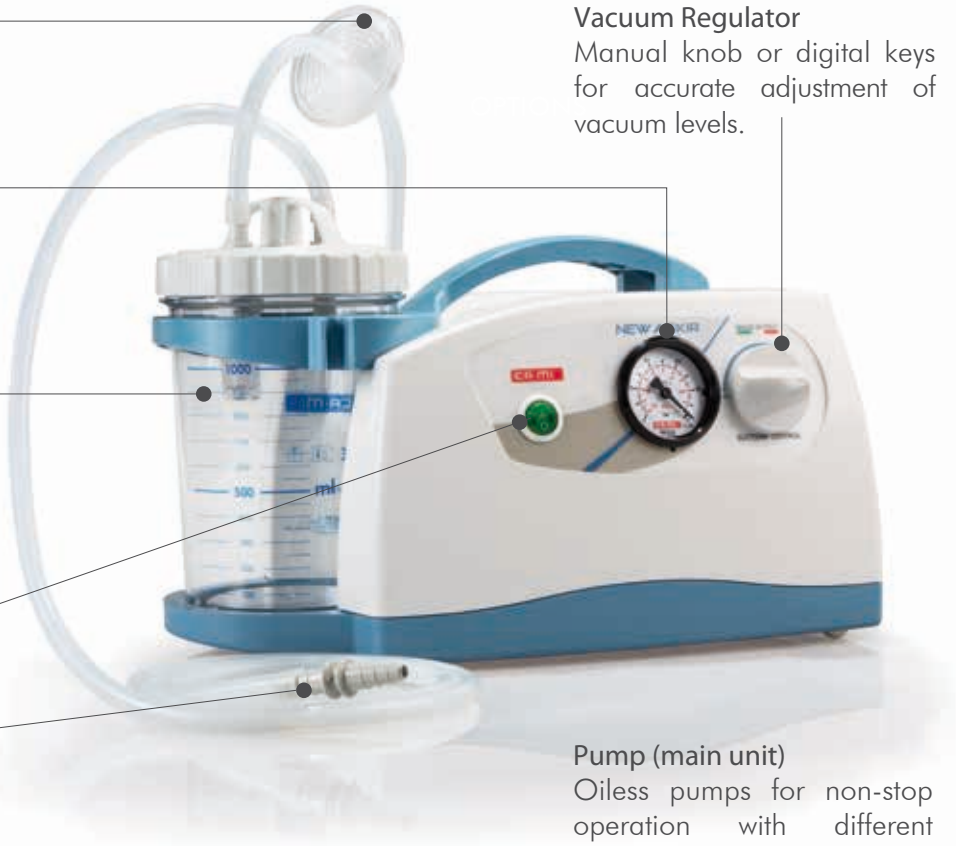
Antibacterial/Hydrophobic Filter
Single-patient filters to avoid cross contaminations and liquid passage to the pump.

Vacuum Gauge
Analogic display in different diameters with graduated scale in mmHg and kPa (interval by 5) or digital LCD.

Liquid Collection Jar
Single or multiple containers in different sizes and materials, reusable or disposable. Provided with cover and overflow valve system.

ON/OFF Switch
Mechanical or digital switch.

Conical Connector
Different diameters to connect any type of cannula.



Vacuum Regulator
Manual knob or digital keys for accurate adjustment of vacuum levels.

Pump (main unit)
Oiless pumps for non-stop operation with different suction capacities, from 15 l/min to 90 l/min.

Handle for easy displacement and **rear compartment** for accessory storage.

Safety Trap Bottle constitutes an additional protection of the pump besides the overflow valve system inside every jar.

MPR System(Multi-Purpose Rail)
Easy interchange of CA-MI accessories, such as rings of various diameters to accommodate jars of different sizes and types, safety trap bottles, cannula holders or a standard medical rail where to hook any accessory by means of standard clamps.

4 x twin **antistatic castors** Ø75mm with brakes with 360° swivel.

MAIN FEATURES

DESK-TYPE suction units	 NEW ASPIRET	NEW ASKIR 20	 NEW ASKIR 30	NEW ASKIR 30 PROXIMITY
Power Feeding	230V / 50-60Hz 120-127V / 60Hz	230V / 50-60Hz	230V / 50-60Hz 110-127V / 60Hz	230V / 50-60Hz
Max Air Flow (wtihout accessories)	15 l/min	16 l/min	40 l/min	40 l/min
Max Vacuum	-563 mmHg	-563 mmHg	-600 mmHg	-600 mmHg
Operation	Non-stop approved	Non-stop approved	Non-stop approved	Non-stop approved
Proximity (touchless ON/OFF)				YES

DESK-TYPE BATTERY OPERATED suction units	 ASKIR 230/12V BR	 ASKIR 36 BR	 ASKIR 36 LI-ION	 ASKIR 118 ASKIR 118 WM BASIC	 ASKIR 118 ASKIR 118 WM
AC/DC Universal adapter 100-240V / 50-60Hz	YES	YES	YES	YES	YES
Car Adapter 12V	YES	YES	YES	YES (except WM model)	YES (except WM model)
Ambulance wall mount (12V 4A) with support and recharge functions				YES (WM model only)	YES (WM model only)
Wall mount with support function only	Optional	Optional	Optional		
Type of battery	Lead	Lead	Lithium-Ion	Lithium-Ion	Lithium-Ion
Battery Autonomy	80 min	60 min	70 min	70 min	70 min
Recharge Time	240 min	240 min	360 min	360 min	360 min
Max Air Flow (wtihout accessories)	16 l/min	36 l/min	36 l/min	36 l/min	26 l/min
Max Vacuum	-563 mmHg	-600 mmHg	-600 mmHg	-563 mmHg	-563 mmHg
10G certified				YES (WM model only)	YES (WM model only)
Energy-saving			YES	YES	YES
Proximity (touchless ON/OFF)			YES	YES	YES
Carrying bag	Optional	Optional	Optional	YES	YES

MAIN FEATURES

EMERGENCY suction units	 NEW ASKIR 12V	 NEW EMIVAC
Power Feeding	12V CAR ADAPTER	FOOT OPERATED

ON CASTORS suction units	 ASKIR C30	 NEW HOSPIVAC 350	NEW HOSPIVAC 400
Power Feeding	220-230V / 50-60Hz	220-230V / 50-60Hz 110-127V / 60Hz	220-230V / 50-60Hz
Max Air Flow (wtihout accessories)	40 l/min	60 l/min	90 l/min
Max Vacuum	-600 mmHg	-675 mmHg	-675 mmHg
Operation	Non-stop approved	Non-stop approved	Non-stop approved
Options	Footswitch	Footswitch Change-Over	Footswitch Change-Over

ON CASTORS BATTERY OPERATED suction units	 ASKIR C30 BR	 HOSPIVAC BR
AC/DC Universal adapter	YES	NO
Power Feeding	*100-240V 50-60Hz*	*220-230V 50-60Hz*
Type of battery	Lead	Lead
Battery Autonomy	60 min	250 min
Recharge Time	240 min	480 min
Energy-saving		YES
Max Air Flow (wtihout accessories)	36 l/min	50 l/min
Max Vacuum	-600 mmHg	-637,5 mmHg

NEW ASPIRET

MAIN APPLICATIONS

- ENT
- Home Care
- Room/Ward
- Tracheostomy

CE 0123

NEW ASPIRET is suitable for nasal, oral and endotracheal aspiration of bodily fluids (mucus or catarrh) from adults and children. Indicated for tracheotomized patients, minor surgical applications and post-operative therapy, NEW ASPIRET finds application in out-patient and in-patient care, elderly care and in private care.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 6x10mm (autoclavable) - Patient Tube length 140cm
- Conical Connector ø 8-9-10mm
- Antibacterial & Hydrophobic Filter (single-patient)
- CH20 Canula
- Power Cord with Schuko plug

OPTIONS

- Stand on 5 Castors Ø 50mm with Brakes (antistatic upon request)	REF 27731
- Carrying Bag (for 1000ml jar)	SP 0207/02
- Carrying Bag (for 2000ml jar)	SP 0207
- Yankauer Handle Flat Tip with Hole	2044403
- Yankauer Handle Crown Tip with Hole	2044401
- Yankauer Tube L= 180	204413018

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz or 120-127V / 60Hz
ISO 10079-1 Classification	HIGH VACUUM / LOW FLOW
Max Vacuum (adjustable)	-0.75 bar -75 kPa -563 mmHg (value at sea level - different altitudes may affect it)
Max free air flow rate	15 l/min
Noise Level	59,6 dBA
Duty cycle	Non-stop operation
IP Code	IP21
Weight	kg 2.95 (unit packed with all accessories)
Size	cm 19 x 23 x 15
Years of Warranty	2
Shipping carton	4
Place of Manufacturing	Italy

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MADE IN ITALY

AVAILABLE CONFIGURATIONS

RE 310001	NEW ASPIRET with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310001/01	NEW ASPIRET with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310001/19	NEW ASPIRET with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 310001/20	NEW ASPIRET with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 310002	NEW ASPIRET with 1000ml Flovac® Disposable Liner
RE 310002/01	NEW ASPIRET with 2000ml Flovac® Disposable Liner

NEW ASKIR 20

MAIN APPLICATIONS

- ENT
- Home Care
- Room/Ward
- Tracheostomy

CE 0123

NEW ASKIR 20 is suitable for nasal, oral and endotracheal aspiration of bodily fluids (mucus or catarrh) from adults and children. Indicated for tracheotomized patients, minor surgical applications and post-operative therapy, NEW ASKIR 20 finds application in out-patient and in-patient care, elderly care and in private care.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 6x10mm (autoclavable) - Patient Tube length 140cm
- Conical Connector ø 8-9-10mm
- Antibacterial & Hydrophobic Filter (single-patient)
- CH20 Canula
- Power Cord with Schuko plug

OPTIONS

- Stand on 5 Castors Ø 50mm with Brakes (antistatic upon request)	REF 27730
- Carrying Bag (for 1000ml jar)	SP 0207/02
- Carrying Bag (for 2000ml jar)	SP 0207
- Wall Mount	27736
- Yankauer Handle Flat Tip with Hole	2044403
- Yankauer Handle Crown Tip with Hole	2044401
- Yankauer Tube L= 180	204413018

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz
ISO 10079-1 Classification	HIGH VACUUM / LOW FLOW
Max Vacuum (adjustable)	-0.75 bar -75 kPa -563 mmHg (value at sea level - different altitudes may affect it)
Max free air flow rate	16 l/min
Noise Level	60,5 dBA
Duty cycle	Non-stop operation
IP Code	IP21
Weight	kg 3.49 (unit packed with all accessories)
Size	cm 35 x 18 x 21
Years of Warranty	2
Shipping carton	3
Place of Manufacturing	Italy

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AVAILABLE CONFIGURATIONS

RE 310100/12	NEW ASKIR 20 with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310100/13	NEW ASKIR 20 with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310100/64	NEW ASKIR 20 with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 310100/70	NEW ASKIR 20 with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 310101/12	NEW ASKIR 20 with 1000ml Flovac® Disposable Liner
RE 310101/13	NEW ASKIR 20 with 2000ml Flovac® Disposable Liner

NEW ASKIR 30

MAIN APPLICATIONS

- Endoscopy
- Gastroenterology
- General Surgery
- Home-Care
- Obstetrics
- Room / Ward
- Veterinary

CE 0123

NEW ASKIR 30 is suitable for nasal, oral and endotracheal aspiration of bodily fluids (mucus or catarrh) from adults and children. Indicated for tracheotomized patients, surgical applications and post-operative therapy, NEW ASKIR 30 finds application in out-patient and in-patient care, elderly care, in private care and at professional level due to its powerful suction capacity of 40 l/min.
The newly-designed ergonomic handle ensures a comfortable and secure grip.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 6x10mm (autoclavable) - Patient Tube length 140cm
- Conical Connector ø 8-9-10mm
- Antibacterial & Hydrophobic Filter (single-patient)
- CH20 Canula
- Power Cord with Schuko plug

OPTIONS

- Stand on 5 Castors Ø 50mm with Brakes (antistatic upon request)	REF 27730
- Carrying Bag (for 1000ml jar)	SP 0207/02
- Carrying Bag (for 2000ml jar)	SP 0207
- Footswitch	SP 0068/01
- Wall Mount	27736
- Yankauer Handle Flat Tip with Hole	2044403
- Yankauer Handle Crown Tip with Hole	2044401
- Yankauer Tube L= 180	204413018

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz or 110-127V / 60Hz
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max Vacuum (adjustable)	-0.80 bar -80 kPa -600 mmHg (value at sea level - different altitudes may affect it)
Max free air flow rate	40 l/min
Noise Level	60,5 dBA
Duty cycle	Non-stop operation
IP Code	IP21
Weight	kg 4.15 (unit packed with all accessories)
Size	cm 35 x 18 x 21
Years of Warranty	2
Shipping carton	3
Place of Manufacturing	Italy

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AVAILABLE CONFIGURATIONS

RE 310100/02	NEW ASKIR 30 with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310100/03	NEW ASKIR 30 with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310100/74	NEW ASKIR 30 with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 310100/63	NEW ASKIR 30 with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 310101/02	NEW ASKIR 30 with 1000ml Flovac® Disposable Liner
RE 310100/53	NEW ASKIR 30 with 2000ml Flovac® Disposable Liner

NEW ASKIR 30 Proximity

MAIN APPLICATIONS

- Endoscopy
- Gastroenterology
- General Surgery
- Home-Care
- Obstetrics
- Room / Ward
- Veterinary

CE 0123

NEW ASKIR 30 Proximity is suitable for nasal, oral and endotracheal aspiration of bodily fluids (mucus or catarrh) from adults and children. Indicated for tracheotomized patients, surgical applications and post-operative therapy, NEW ASKIR 30 Proximity finds application in out-patient and in-patient care, elderly care, in private care and at professional level due to its powerful suction capacity of 40 l/min. The newly-designed ergonomic handle ensures a comfortable and secure grip.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 6x10mm (autoclavable) - Patient Tube length 140cm
- Conical Connector ø 8-9-10mm
- Antibacterial & Hydrophobic Filter (single-patient)
- CH20 Canula
- Power Cord with Schuko plug

OPTIONS

- Stand on 5 Castors Ø 50mm with Brakes (antistatic upon request)	REF 27730
- Carrying Bag (for 1000ml jar)	SP 0207/02
- Carrying Bag (for 2000ml jar)	SP 0207
- Footswitch	SP 0068/01
- Wall Mount	27736
- Yankauer Handle Flat Tip with Hole	2044403
- Yankauer Handle Crown Tip with Hole	2044401
- Yankauer Tube L= 180	204413018

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max Vacuum (adjustable)	-0.80 bar -80 kPa -600 mmHg (value at sea level - different altitudes may affect it)
Max free air flow rate	40 l/min
Noise Level	60,5 dBA
Duty cycle	Non-stop operation
IP Code	IP21
Weight	kg 4.16 (unit packed with all accessories)
Size	cm 35 x 18 x 21
Years of Warranty	2
Shipping carton	3
Place of Manufacturing	Italy

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AVAILABLE CONFIGURATIONS

RE 310100/02	NEW ASKIR 30 Proximity with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310100/03	NEW ASKIR 30 Proximity with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310100/75	NEW ASKIR 30 Proximity with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 310100/62	NEW ASKIR 30 Proximity with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 310101/02	NEW ASKIR 30 Proximity with 1000ml Flovac® Disposable Liner
RE 310100/53	NEW ASKIR 30 Proximity with 2000ml Flovac® Disposable Liner

ASKIR 36 BR

MAIN APPLICATIONS

- Emergency Dept.
- Home-Care
- Patient Transfer
- Room / Ward
- Tracheostomy
- Veterinary

Internal Rechargeable Battery

CE 0123

ASKIR 36BR is a portable suction unit for professional use and with a powerful aspiration of max 36 l/min, conceived to be lightweight for easy transport. Three different options for operation: AC/DC adapter, internal lead or lithium-ion rechargeable battery and 12V make it a versatile suction unit approved for NON-STOP operation without overheating. Provided with visual and acoustic alarm indicating low battery level. The newly-designed ergonomic handle ensures a comfortable and secure grip.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm
- Conical Connector ø10-11-12mm
- Antibacterial & Hydrophobic Filter (single-patient)
- Internal rechargeable Lead Battery
- Universal switching power adapter and Cable + 12V Car Adapter

OPTIONS

- Stand on 5 Castors Ø 50mm with Brakes (antistatic upon request)	REF 27730
- Carrying Bag (for 1000ml jar)	SP 0207/02
- Carrying Bag (for 2000ml jar)	SP 0207
- Wall Mount Brackets	27736
- Footswitch	SP 0068/01
- Yankauer Handle Flat Tip with Hole	2044403
- Yankauer Handle Crown Tip with Hole	2044401
- Yankauer Tube L= 180	204413018

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	14V ⎓ 4A by AC/DC Universal Adapter 100-240V / 50-60Hz - 100VA (model UE60-140429SPA1)
	12V ⎓ 4A Lead rechargeable battery - Autonomy 60 min. - Recharging Time 4 hours
	12V ⎓ 4A Car adapter
ON/OFF Switch	Mechanical switch
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max Vacuum (adjustable)	-0.80 bar -80 kPa -600 mmHg (value at sea level - different altitudes may affect it)
Max free air flow rate	36 l/min
Noise Level	65,5 dBA (with jar) / 68,5 dBA (without jar)
Duty cycle	Non-stop operation (by mains only)
IP Code	IP21
Weight	kg 5.31 (unit packed with all accessories)
Size	cm 35 x 18 x 21
Years of Warranty	2
Shipping carton	3
Place of Manufacturing	Italy

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AVAILABLE CONFIGURATIONS

RE 410200/03	ASKIR 36BR with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 410200/09	ASKIR 36BR with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 410200/10	ASKIR 36BR with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 410200/12	ASKIR 36BR with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 410201	ASKIR 36BR with 1000ml Flovac® Disposable Liner
RE 410201/01	ASKIR 36BR with 2000ml Flovac® Disposable Liner

NEW ASKIR 36 LI-ION

MAIN APPLICATIONS

- Emergency Dept.
- Home-Care
- Patient Transfer
- Room / Ward
- Tracheostomy
- Veterinary

PROXIMITY
NO-TOUCH ON/OFF

Internal Rechargeable Battery

CE 0123

NEW ASKIR 36 LI-ION is a portable suction unit for professional use and with a powerful aspiration of max 36 l/min, conceived to be lightweight for easy transport. Three different options for operation: AC/DC adapter, internal lead or lithium-ion rechargeable battery and 12V make it a versatile suction unit approved for NON-STOP operation without overheating. Provided with Li-Ion battery, this model is equipped with a pressure sensor placed in the PCB reduces the speed of the motor when no vacuum is detected and therefore no aspiration is taking place, and with PROXIMITY function to switch ON/OFF without touch. The newly-designed ergonomic handle ensures a comfortable and secure grip. The newly-designed ergonomic handle ensures a comfortable and secure grip.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm
- Conical Connector ø10-11-12mm
- Antibacterial & Hydrophobic Filter (single-patient)
- Internal rechargeable Lithium-ion Battery
- Universal switching power adapter and Cable + 12V Car Adapter

OPTIONS

- Stand on 5 Castors Ø 50mm with Brakes (antistatic upon request)	REF 27730
- Carrying Bag (for 1000ml jar)	SP 0207/02
- Carrying Bag (for 2000ml jar)	SP 0207
- Wall Mount Brackets	27736
- Footswitch	SP 0068/01
- Yankauer Handle Flat Tip with Hole	2044403
- Yankauer Handle Crown Tip with Hole	2044401
- Yankauer Tube L= 180	204413018

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	14V ⎓ 4A by AC/DC Universal Adapter 100-240V / 50-60Hz - 100VA (model UE60-140429SPA1)
	14,8V ⎓ 5,2A Li-Ion rechargeable battery - Autonomy 70 min. - Recharging Time 6 hours
	12V ⎓ 4A Car adapter
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max Vacuum (adjustable)	-0.80 bar -80 kPa -600 mmHg (value at sea level - different altitudes may affect it)
Max free air flow rate	36 l/min
Noise Level	60 dBA
ON/OFF Switch	Soft-Touch switch
Duty cycle	Non-stop operation (by mains only)
IP Code	IP22
Weight	kg 4.31 (unit packed with all accessories)
Size	cm 35 x 18 x 21
Years of Warranty	2
Shipping carton	2
Place of Manufacturing	Italy

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AVAILABLE CONFIGURATIONS

RE 410205	NEW ASKIR 36BR LI-ION with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 410205/01	NEW ASKIR 36BR LI-ION with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 410205/04	NEW ASKIR 36BR LI-ION with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 410205/05	NEW ASKIR 36BR LI-ION with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 410205/02	NEW ASKIR 36BR LI-ION with 1000ml Flovac® Disposable Liner
RE 410205/03	NEW ASKIR 36BR LI-ION with 2000ml Flovac® Disposable Liner

NEW ASKIR 118

MAIN APPLICATIONS

- Home-Care
- Patient Transfer
- Room/Ward
- Tracheostomy
- Emergency
- Veterinary

Wall mount for ambulance

- Ambulance Car
- Emergency
- Rescue

NEW ASKIR 118 is an electric medical device for the nasal, oral and tracheal aspiration of body fluids in children or adults. It is available in two configurations, one specifically designed for use in ambulance car and emergency and the other for home-care and hospital applications. Large LCD for clear reading of vacuum values along with soft keys for vacuum adjustment increase the accuracy of aspiration. Smart operation thanks to the combination of the lightweight lithium-ion battery with the innovating FEEDBACK system that controls and manages the power of aspiration, providing a long autonomy of the battery and quiet noise level during operation. The PROXIMITY function to switch ON or OFF the device without touch prevents and avoids cross-contamination in-between patients. The unit is equipped with a long-life brushless motor eliminating any type of smell and coal residuals. The NEW ASKIR 118 series is available with various options of jar materials, such as the autoclavable polycarbonate (121°C), or the FLOVAC® disposable liners, or the APEC® that can resist up to 143°C. The ambulance wall mount is 10g dynamically tested according to the EN 1789:2007 last edition European Norm.

DIGITAL VERSION ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm + Conical Connector ø 10-11-12mm
- Antibacterial & Hydrophobic Filter (single-patient) + CH20 Canula
- Universal switching power adapter (100-240V / 50-60Hz) and Cable
- 12V Car Adapter for RE410151/XX code only
- Wall mount for ambulance (size cm 20x16x16) for RE410150/XX code only
- Protective Carrying Case (included for RE410150/XX / option for RE410151/XX code SP 0207/01)

PROXIMITY NO-TOUCH ON/OFF

ENERGY SA VING

Internal Rechargeable Battery

DIGITAL VERSION TECHNICAL FEATURES

Brushless Motor	Oiless and maintenance-free piston pump
Power Feeding	14V ⎓ 4A by AC/DC Universal Adapter 100-240V / 50-60Hz - 100VA (model UE60-140429SPA1)
	14,8V ⎓ 5,2A Li-Ion rechargeable battery - Autonomy 70 min. - Recharging Time 6 hours
	12V ⎓ 4A Car adapter for RE410151/XX code only
	Wall mount for ambulance (12V ⎓ 4A) for RE410150/XX code only
Max Vacuum (adjustable)	-0.75 bar -75 kPa -563 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	26 l/min
Noise level	min. 46,7 dB max. 61,8 dB (depending on power supply)
Duty cycle	Non-stop operation (by mains only)
IP Code	IP22
Weight	kg 4.07 (unit packed with all accessories)
Size	cm 35 x 15 x 19
Years of Warranty	2
Shipping carton	2
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

DIGITAL VERSION AVAILABLE CONFIGURATIONS

	ASKIR 118	ASKIR 118 WM
NEW ASKIR 118 with 1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410151	RE 410150
NEW ASKIR 118 with 1000ml Autoclavable Jar in Apec®(max 143°C)	RE 410151/05	RE 410150/05
NEW ASKIR 118 with 1000ml Flovac®Disposable Liner	RE 410151/02	RE 410150/02

CE 0123

(The warranty lapses immediately if the unit is used without all the required accessories or with non-original CA-MI accessories)

NEW ASKIR 118 BASIC

MAIN APPLICATIONS

- Home-Care
- Patient Transfer
- Room/Ward
- Tracheostomy
- Emergency
- Veterinary

- Ambulance Car
- Emergency
- Rescue

Wall mount for ambulance

NEW ASKIR 118 BASIC is an electric medical device for the nasal, oral and tracheal aspiration of body fluids in children or adults. It is available in two configurations, one specifically designed for use in ambulance car and emergency and the other for home-care and hospital applications. The unit is equipped with a long-life oiless piston pump motor providing 36 l/min suction capacity. The NEW ASKIR 118 BASIC series is available with various options of jar materials, such as the autoclavable polycarbonate (121°C), or the FLOVAC® disposable liners, or the APEC® that can resist up to 143°C. The ambulance wall mount is 10g dynamically tested according to the EN 1789:2007 last edition European Norm.

ANALOGIC VERSION ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm + Conical Connector ø 10-11-12mm
- Antibacterial & Hydrophobic Filter (single-patient) + CH20 Canula
- Universal switching power adapter (100-240V 50/60Hz) and Cable
- 12V Car Adapter for RE410171/XX code only
- Wall mount for ambulance (size cm 20x16x16) for RE410170/XX code only
- Protective Carrying Case (included for RE410170/XX / option for RE410171/XX code SP 0207/01)

PROXIMITY NO-TOUCH ON/OFF

ENERGY SAVING

Internal Rechargeable Battery

ANALOGIC VERSION TECHNICAL FEATURES

Brushless Motor	Oiless and maintenance-free piston pump
Power Feeding	14V ⎓ 4A by AC/DC Universal Adapter 100-240V / 50-60Hz - 100VA (model UE60-140429SPA1)
	14,8V ⎓ 5,2A Li-Ion rechargeable battery - Autonomy 70 min. - Recharging Time 6 hours
	12V ⎓ 4A Car adapter for RE410171/XX code only
	Wall mount for ambulance (12V⎓ 4A) for RE410170/XX code only
Max Vacuum (adjustable)	-0.75 bar -75 kPa -563 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	36 l/min
Max free air flow rate	min. 54,7 dB max. 68,2 dB (depending on power supply)
Duty cycle	Non-stop operation (by mains only)
IP Code	IP22
Weight	kg 2.50 (unit packed with all accessories)
Size	cm 35 x 15 x 19
Years of Warranty	2
Shipping carton	2
Place of Manufacturing	Italy

Italian Medical Touch
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ANALOGIC VERSION AVAILABLE CONFIGURATIONS

	118 BASIC	118 BASIC WM
NEW ASKIR 118 BASIC with 1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410171	RE 410170
NEW ASKIR 118 BASIC with 1000ml Autoclavable Jar in Apec®(max 143°C)	RE 410171/03	RE 410170/03
NEW ASKIR 118 BASIC with 1000ml Flovac®Disposable Liner	RE 410171/01	RE 410170/01

CE 0123

NEW ASKIR 230/12V BR

MAIN APPLICATIONS

- Emergency Dept.
- Home-Care
- Patient Transfer
- Room / Ward
- Tracheostomy
- Veterinary

Internal Rechargeable Battery

CE 0123

NEW ASKIR 230/12V BR is an electric suction unit for the aspiration of body liquids, oral, nasal and tracheal aspiration in adults or children. Suitable for emergency applications and for post-operative therapy, both in professional environment and home-care.
Three different options for operation: AC/DC adapter, rechargeable battery and 12V make it a versatile suction unit approved for NON-STOP operation without overheating. Provided with visual and acoustic alarm indicating low battery level.
The newly-designed ergonomic handle ensures a comfortable and secure grip.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 6x10mm (autoclavable) - Patient Tube length 140cm
- Conical Connector ø 8-9-10mm
- Antibacterial & Hydrophobic Filter (single-patient) + CH20 Canula
- AC/DC Universal Adapter + Power Cord with European plug
- 12V Car Adapter

OPTIONS

- Stand on 5 Castors Ø 50mm with Brakes (antistatic upon request)	REF 27730
- Carrying Bag (for 1000ml jar)	SP 0207/02
- Carrying Bag (for 2000ml jar)	SP 0207
- Wall Mount	27736
- Yankauer Handle Flat Tip with Hole	2044403
- Yankauer Handle Crown Tip with Hole	2044401
- Yankauer Tube L= 180	204413018

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	14V ⎓ 4A by AC/DC Universal Adapter 100-240V / 50-60Hz - 100VA (model UE60-140429SPA1)
	12V ⎓ 4A Internal rechargeable Pb battery - Autonomy 80 min. - Recharging Time 4 hours
	12V ⎓ 1,9A Car adapter
ISO 10079-1 Classification	HIGH VACUUM / LOW FLOW
Max Vacuum (adjustable)	-0.75 bar -75 kPa -563 mmHg (value at sea level - different altitudes may affect it)
Max free air flow rate	16 l/min
Noise Level	63,0 dBA
Duty cycle	Non-stop operation (by mains only)
IP Code	IP21
Weight	kg 4.55 (unit packed with all accessories)
Size	cm 35 x 18 x 21
Years of Warranty	2
Shipping carton	3
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

AVAILABLE CONFIGURATIONS

RE 310211	NEW ASKIR 230/12V BR with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310211/01	NEW ASKIR 230/12V BR with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310211/06	NEW ASKIR 230/12V BR with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 310211/11	NEW ASKIR 230/12V BR with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 310211/03	NEW ASKIR 230/12V BR with 1000ml Flovac® Disposable Liner
RE 310211/04	NEW ASKIR 230/12V BR with 2000ml Flovac® Disposable Liner

NEW ASKIR 30 12V MAIN APPLICATIONS

- Ambulance Car
- Emergency

NEW EMIVAC MAIN APPLICATIONS

- Ambulance Car
- Emergency Dept.
- Field Hospital
- Obstetrics

CE 0123

NEW ASKIR 30 12V is a desk-type electric suction unit for the aspiration of body liquids, oral, nasal and tracheal aspiration in adults or children. Designed for use in ambulance car. Equipped with aspiration regulator and vacuum indicator located on the front panel.
Operates by 12V DC only!

NEW EMIVAC is a portable foot-operated suction unit suitable for emergency aspiration. No lubrication or battery change are needed and it's always ready for use. It can be used for soft aspirations such as tracheal suction and on small children and up to 300 mmHg. Provided with a polycarbonate 400 ml autoclavable jar with overflow valve.
Foot-operated only!

ACCESSORIES INCLUDED

NEW ASKIR 30 12V

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 6x10mm (autoclavable) - Patient Tube length 140cm
- Conical Connector ø 8-9-10 mm
- Antibacterial & Hydrophobic Filter (single-patient)
- CH20 Canula
- 12V Car Adapter

NEW EMIVAC

- Liquid Collection Jar with overflow valve system
- Silicone Tubes ø 6x10mm (autoclavable) - Patient Tube length 140cm
- Conical Connector ø 8-9-10 mm
- Antibacterial & Hydrophobic Filter (single-patient)

TECHNICAL FEATURES

TECHNICAL FEATURES	NEW ASKIR 30 12V	NEW EMIVAC
Motor	Oiless and maintenance-free piston pump	/
Power Feeding	12V ⎓	Manual (foot-operated)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW	MEDIUM VACUUM - 22l/min
Max Vacuum* (adjustable)	-0.75 bar -75 kPa -563 mmHg	-0.40 bar -40 kPa -300 mmHg
	*(value at sea level - different altitudes may affect it)	
Max free air flow rate	25 l/min	22 l/min
Noise Level	61,5 dBA	/
Duty cycle	Ton: 20min - Toff: 40min	Foot-operated
Weight	kg 2.50	kg 1.15
Size	cm 35 x 21 x 18	cm 22 x 16 x 8
Years of Warranty	2	2
Shipping carton	4	6
Place of Manufacturing	Italy	Italy

Italian Medical Touch
MADE IN ITALY

AVAILABLE CONFIGURATIONS

RE 310150/02	NEW ASKIR 30 12V with 1000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310150/05	NEW ASKIR 30 12V with 2000ml Autoclavable Jar in Makrolon® (max 121°C)
RE 310150/10	NEW ASKIR 30 12V with 1000ml Autoclavable Jar in Apec® (max 143°C)
RE 310150/11	NEW ASKIR 30 12V with 2000ml Autoclavable Jar in Apec® (max 143°C)
RE 310150/12	NEW ASKIR 30 12V with 1000ml Flovac® Disposable Liner
RE 310150/13	NEW ASKIR 30 12V with 2000ml Flovac® Disposable Liner
RE 310300	NEW EMIVAC with 400 ml autoclavable jar in polycarbonate

ASKIR C30 BR

MAIN APPLICATIONS

- Emergency Dept.
- Endoscopy
- Gastroenterology
- General Surgery
- Obstetrics
- Dental Practice

Internal Rechargeable Battery

CE 0123

ASKIR C30 BR is a portable suction unit for the aspiration of body liquids, oral, nasal and tracheal aspiration in adults or children. For professional use and with a powerful aspiration of max 36l/min. ASKIR C30 BR comes with double collection jars and on a stand with five antistatic castors for easy transport. Two different options for operation: AC/DC adapter and rechargeable battery in case of power black out make it a versatile suction unit approved for NON-STOP operation without overheating. Provided with visual and acoustic alarm indicating low battery level, the main unit is also equipped with vacuum-meter (mmHg & kPa) and vacuum regulator.

ACCESSORIES INCLUDED

- Liquid Collection Jar with overflow valve system (different options, see below)
- Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm
- Conical Connector ø 10-11-12mm
- Antibacterial & Hydrophobic Filter (single-patient)
- Universal switching Power Adapter (100-240V/50-60Hz) + Power Cord

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	14V ⎓ 4A by AC/DC Universal Adapter 100-240V / 50-60Hz - 100VA (model UE60-140429SPA1)
	12V ⎓ 4A Internal rechargeable Pb battery - Autonomy 60 min. - Recharging Time 4 hours
Max Vacuum (adjustable)	-0.80 bar -80 kPa -600 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	36 l/min
Noise Level	65,5 dBA (with jar) / 68,5 dBA (without jar)
Duty cycle	Non-stop operation (by mains only)
Weight	kg 12.90 (unit packed with all accessories)
Size	cm 32 x 30 x 99
Years of Warranty	2
Shipping carton	1
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

AVAILABLE CONFIGURATIONS

RE 410251	ASKIR C30 BR with 2x2000 ml autoclavable jars in polycarbonate Makrolon 2858
RE 410251/01	ASKIR C30 BR with 2x2000 ml Flovac® disposable liners and reusable containers
	Jars in APEC® autoclavable up to 143°C available upon request

ASKIR C30

MAIN APPLICATIONS

- Emergency Dept.
- Endoscopy
- Gastroenterology
- General Surgery
- Obstetrics
- Dental Practice

CE 0123

ASKIR C30 is a portable suction unit on castors for the aspiration of body liquids, oral, nasal and tracheal aspiration in adults or children. For professional use and with a powerful aspiration of max 40 l/min, ASKIR C30 comes with double collection jars and on a stand with five castors for easy transport. Main unit equipped with vacuum-meter (mmHg & kPa) and vacuum regulator.

ACCESSORIES INCLUDED	BASIC	FS
Liquid Collection Jar with overflow valve system (different options, see below)	o	o
Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm	o	o
Conical Connector ø 10-11-12mm	o	o
Antibacterial & Hydrophobic Filter (single-patient) + CH20 Canula	o	o
Power Cord with Schuko plug	o	o
Footswitch (may be ordered at a later time)		o

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz
Max Vacuum (adjustable)	-0.80 bar -80 kPa -600 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	40 l/min
Noise Level	61,5 dBA
Duty cycle	Non-stop operation
Weight	kg 9.06 (unit packed with all accessories)
Size	cm 32 x 30 x 99
Years of Warranty	2
Shipping carton	1
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

AVAILABLE CONFIGURATIONS

RE 410250	ASKIR C30 BASIC with 2x2000 ml autoclavable jars in polycarbonate Makrolon 2858
RE 410250/01	ASKIR C30 FS with 2x2000 ml autoclavable jars in polycarbonate Makrolon 2858 + footswitch
RE 410250/10	ASKIR C30 BASIC with 2x2000 ml Flovac® disposable liners and reusable containers
	Jars in APEC® autoclavable up to 143°C available upon request

NEW HOSPIVAC 350

with new **MPR system** Multi Purpose Rail

See page 24

MAIN APPLICATIONS

- Emergency Dept.
- General Surgery
- Ginecology
- Neurosurgery
- Obstetrics
- Operating Theatre
- Dental Practice

CE 0123

Available in its three configurations, BASIC, FS and FULL, NEW HOSPIVAC 350 has been designed for professional aspiration of bodily fluids, tissues or bones of patients during or after surgery. The state-of-the-art 60 l/min oiless and maintenance-free pump provides high performances with excellent suction capacities and max vacuum built up within a few seconds. A clear dashboard along with a full range of accessories and antistatic castors with brakes make it the ideal device for surgical suction. The new MPR (Multi Purpose Rail) system enhances the versatility of the Hospivac series for easy and quick exchange of different accessories, with no need for tools. In fact, being equipped with five connections, all CA-MI accessories can be easily accommodated, such as rings of various diameters to fit jars of different sizes and types (2L, 3L, 5L), cannula holders or a medical stainless steel rail where to hook any other type of accessory by means of clamps. The new safety trap bottle is also a new standard accessory in the Hospivac series.
The new safety trap bottle is also a new standard accessory in the Hospivac series, bringing up to three the overflow protection systems, besides the valve integrated in the jar and the hydrophobic filter, thus providing the Hospivac series with the highest standards of safety.

AVAILABLE MODELS AND ACCESSORIES INCLUDED	BASIC	FS	FULL
Liquid Collection Jar with overflow valve system (different options, see below)	2	2	2
Rings to accommodate jars (3 sizes depending on the jar)	2	2	2
Safety Trap Bottle (220ml)	1	1	2
Antibacterial & Hydrophobic Filter (single-patient)	1	1	2
Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm	1	1	2
Conical Connector ø 10-11-12mm	1	1	2
Air suction inlet	1	1	2
Footswitch with intermittent or continuous operation		1	1
Change-Over System from jar to jar by soft-touch keys			1
Power Cord with Schuko plug	1	1	1

OPTIONAL ACCESSORIES

Rings available in three sizes:
- 2000 ml autoclavable jars
- 2000 ml and 3000 ml Flovac® disposable systems
- 5000 ml autoclavable jars

Cannula holder to store safely suction tube during operation
Footswitch with vacuum regulation function
Silicone Fetal Vacuum Cups
Standard medical stainless steel rail (25x10 or 30x10) and clamps

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz or 110-127V / 60Hz
Max Vacuum (adjustable)	-0.90 bar -90 kPa -675 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	60 l/min
Noise Level	51,7 dBA
Duty cycle	Non-stop operation
Weight	20 kg (unit alone without accessories)
Size	cm 46 x 42 x 85
Years of Warranty	2
Shipping carton	1
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

(The warranty lapses immediately if the unit is used without all the required accessories or with non-original CA-MI accessories)

NEW HOSPIVAC 400

MAIN APPLICATIONS

- Emergency Dept.
- General Surgery
- Ginecology
- Neurosurgery
- Obstetrics
- Operating Theatre
- Dental Practice

CE 0123

with new **MPR system** Multi Purpose Rail

See page 24

Available in its three configurations, BASIC, FS and FULL, NEW HOSPIVAC 400 has been designed for professional aspiration of bodily fluids, tissues or bones of patients during or after surgery. The state-of-the-art 90 l/min oiless and maintenance-free pump provides high performances with excellent suction capacities and max vacuum built up within a few seconds. A clear dashboard along with a full range of accessories and antistatic castors with brakes make it the ideal device for surgical suction. The new MPR (Multi Purpose Rail) system enhances the versatility of the Hospivac series for easy and quick exchange of different accessories, with no need for tools. In fact, being equipped with five connections, all CA-MI accessories can be easily accommodated, such as rings of various diameters to fit jars of different sizes and types (2L, 3L, 5L), cannula holders or a medical stainless steel rail where to hook any other type of accessory by means of clamps. The new safety trap bottle is also a new standard accessory in the Hospivac series. The new safety trap bottle is also a new standard accessory in the Hospivac series, bringing up to three the overflow protection systems, besides the valve integrated in the jar and the hydrophobic filter, thus providing the Hospivac series with the highest standards of safety.

AVAILABLE MODELS AND ACCESSORIES INCLUDED	BASIC	FS	FULL
Liquid Collection Jar with overflow valve system (different options, see below)	2	2	2
Rings to accommodate jars (3 sizes depending on the jar)	2	2	2
Safety Trap Bottle (220ml)	1	1	2
Antibacterial & Hydrophobic Filter (single-patient)	1	1	2
Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm	1	1	2
Conical Connector ø 10-11-12mm	1	1	2
Air suction inlet	1	1	2
Footswitch with intermittent or continuous operation		1	1
Change-Over System from jar to jar by soft-touch keys			1
Power Cord with Schuko plug	1	1	1

OPTIONAL ACCESSORIES

Rings available in three sizes:
- 2000 ml autoclavable jars
- 2000 ml and 3000 ml Flovac® disposable systems
- 5000 ml autoclavable jars

Cannula holder to store safely suction tube during operation
Footswitch with vacuum regulation function
Silicone Fetal Vacuum Cups
Standard medical stainless steel rail (25x10 or 30x10) and clamps

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz
Max Vacuum (adjustable)	-0.90 bar -90 kPa -675 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	90 l/min
Noise Level	46,4 dBA
Duty cycle	Non-stop operation
Weight	21 kg (unit alone without accessories)
Size	cm 46 x 42 x 85
Years of Warranty	2
Shipping carton	1
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

CONFIGURATIONS

NEW HOSPIVAC 350		AUTOCLAVABLE JARS						DISPOSABLE LINERS			
		Makrolon® 2858 (max 121°C)		Polysulfone (PSU)		Apec® (max 143°C)		Flovac® systems			
REF.	MODEL	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 3000 ml	FOOT SWITCH	CHANGE OVER
RE 410356	BASIC 2	■									
RE 410356/06	FS 2	■								■	
RE 410356/01	FULL 2	■								■	■
RE 410356/39	BASIC 5		■								
RE 410356/40	FS 5		■							■	
RE 410356/41	FULL 5		■							■	■
RE 410356/59	BASIC PSU 2			■							
RE 410356/60	FS PSU 2			■						■	
RE 410356/61	FULL PSU 2			■						■	■
RE 410356/62	BASIC PSU 5				■						
RE 410356/63	FS PSU 5				■					■	
RE 410356/64	FULL PSU 5				■					■	■
RE 410356/56	BASIC AP 2					■					
RE 410356/38	FS AP 2					■				■	
RE 410356/55	FULL AP 2					■				■	■
RE 410356/58	BASIC AP 5						■				
RE 410356/54	FS AP 5						■			■	
RE 410356/43	FULL AP 5						■			■	■
RE 410356/27	BASIC FLOVAC 2							■			
RE 410356/29	FS FLOVAC 2							■		■	
RE 410356/28	FULL FLOVAC 2							■		■	■
RE 410356/02	BASIC FLOVAC 3								■		
RE 410356/09	FS FLOVAC 3								■	■	
RE 410356/30	FULL FLOVAC 3								■	■	■

NEW HOSPIVAC 400		AUTOCLAVABLE JARS						DISPOSABLE LINERS			
		Makrolon® 2858 (max 121°C)		Polysulfone (PSU)		Apec® (max 143°C)		Flovac® systems			
REF.	MODEL	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 5000 ml	2 Jars 2000 ml	2 Jars 3000 ml	FOOT SWITCH	CHANGE OVER
RE 410350	BASIC 2	■									
RE 410350/09	FS 2	■								■	
RE 410350/01	FULL 2	■								■	■
RE 410350/36	BASIC 5		■								
RE 410350/37	FS 5		■							■	
RE 410350/38	FULL 5		■							■	■
RE 410350/57	BASIC PSU 2			■							
RE 410350/58	FS PSU 2			■						■	
RE 410350/59	FULL PSU 2			■						■	■
RE 410350/60	BASIC PSU 5				■						
RE 410350/61	FS PSU 5				■					■	
RE.410350/62	FULL PSU 5				■					■	■
RE 410350/40	BASIC AP 2					■					
RE 410350/46	FS AP 2					■				■	
RE 410350/33	FULL AP 2					■				■	■
RE 410350/48	BASIC AP 5						■				
RE 410350/39	FS AP 5						■			■	
RE 410350/47	FULL AP 5						■			■	■
RE 410350/08	BASIC FLOVAC 2							■			
RE 410350/03	FS FLOVAC 2							■		■	
RE 410350/11	FULL FLOVAC 2							■		■	■
RE 410350/27	BASIC FLOVAC 3								■		
RE 410350/28	FS FLOVAC 3								■	■	
RE 410350/25	FULL FLOVAC 3								■	■	■

NEW HOSPIVAC BR

MAIN APPLICATIONS

- Emergency Dept.
- General Surgery
- Ginecology
- Neurosurgery
- Obstetrics
- Operating Theatre
- Dental Practice

CE 0123

Internal Rechargeable Battery

with new **MPR system** Multi Purpose Rail

See page 24

For environments where a battery back up is required, NEW HOSPIVAC BR is the unique solution for surgeons and professionals, providing high performances along with the internal rechargeable battery capable of operating the unit for for more than 4 hours in absence of mains electricity. With the Energy-Saving function, a pressure sensor placed in the PCB reduces the speed of the motor when the unit is ON and no aspiration is taking place. This extends the autonomy of the battery and reduces the noise level. Designed with fast connectors, the new Multi Purpose Rail enables the operator to easy interchange of accessories, such as rings of various diameters to accommodate jars of any sizes and types, safety trap bottles, cannula holders or a standard medical rail where to hook any accessory by means of clamps.

STANDARD ACCESSORIES INCLUDED

- 2 x Liquid Collection Jar with overflow valve system (different options, see below)
- 2 Sets of Silicone Tubes ø 8x14mm (autoclavable) - Patient Tube length 150cm
- Conical Connector ø 10-11-12mm
- 2 x Antibacterial & Hydrophobic Filter (single-patient)
- Footswitch
- Power Cord with Schuko plug

FUNCTIONS

- Electronic Change-Over System from jar to jar
- Energy-saving
- Internal rechargeable battery and charger
- Footswitch with intermittent or continuous use

OPTIONS

- Vacuum Regulator Footswitch
- Cannula Container
- Silicone Fetal Vacuum Cups

TECHNICAL FEATURES

Motor	Oiless and maintenance-free piston pump
Power Feeding	220-230V / 50-60Hz with internal AC/DC Power Adapter
	Internal Rechargeable Battery (Lead-type 12V ⎓ 20A) Battery Autonomy 250 min. - Recharging Time 8 hours
Max Vacuum (adjustable)	-0.85 bar -85 kPa -637,5 mmHg (value at sea level - different altitudes may affect it)
ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Max free air flow rate	50 l/min
Absorbed Power	90VA
Duty cycle	Non-stop operation (by mains only)
Weight	kg 20
Size	cm 46 x 42 x 85
Years of Warranty	2
Shipping carton	1
Place of Manufacturing	Italy

Italian Medical Touch
MADE IN ITALY

AVAILABLE CONFIGURATIONS

RE 410400	NEW HOSPIVAC BR with 2x2000 ml autoclavable jar in polycarbonate Makrolon 2858
RE 410400/03	NEW HOSPIVAC BR with 2x5000 ml autoclavable jar in polycarbonate Makrolon 2858
RE 410400/01	NEW HOSPIVAC BR with 2x2000 ml Flovac® disposable liner and reusable container
RE 410400/02	NEW HOSPIVAC BR with 2x5000 ml Flovac® disposable liner and reusable container
	Jars in APEC® autoclavable up to 143°C available upon request

MPR system

Thanks to the new MPR System, HOSPIVAC series offer a great versatility to users when it comes to change type of jars for liquid collection, regardless in which configuration the suction unit has been supplied in origin. The table below shows the components of the MPR System.

NEW HOSPIVAC SERIES JARS INTERCHANGE

COMPONENT	DESCRIPTION	REF.
	MPR - Multipurpose Rail with 5 locking slots. Supplied with each Hospivac.	31255
	CAPS to close the locking slots when not in use	31253
	Safety trap bottle (220ml)	***
	RING for 2L autoclavable jar RING for 5L autoclavable jar RING for 2L or 3L Flovac® RING for catheter holder	31254 31254/01 31254/02 31254/03
	Stainless steel standard medical rail, 25x10 Stainless steel standard medical rail, 30x10	*** 23613
	Right HOOK for stainless steel rail Left HOOK for stainless steel rail	31256 31257

ASKIR C30 SERIES JARS INTERCHANGE

EXISTING JARS	TO SWITCH TO 2000 ml autoclavable jars	TO SWITCH TO 4000 ml/5000 ml autoclavable jars	TO SWITCH TO 2000 ml disposable liners	TO SWITCH TO 3000 ml disposable liners
2000 ml autoclavable jars		DO NOT FIT	Ring adapters SP 0078/04 to be removed from existing jar holder	Ring adapters SP 0078/04 to be removed from existing jar holder
2000 ml disposable liners	Ring adapters SP 0078/04 to be inserted into existing jar holder	DO NOT FIT		DO NOT FIT

REUSABLE JARS are equipped with screw cover with handle for easy grip, autoclavable silicone o-ring for tight seal, overflow valve system integrated in the cover, clear graduated scale in ml with 100ml or 200ml intervals, CA-MI branding. Suitable for central vacuum systems and CA-MI suction units.Available in two types of polycarbonate, Makrolon® and Apec®.

REUSABLE JARS in MAKROLON® – FOR STEAM STERILIZATION UP TO 121 °C

	Jar with: cover overflow valve o-ring	Jar	Cover with: overflow valve o-ring	O-ring	Suitable for:
400 ml	RE 210301	RE 210305	RE 210302	RE 210304	EMIVAC
1000 ml	RE 210001/02	RE 210003	RE 210352/01	RE 210354	ASPIRET ASKIR series (all except C30 series) Central Vacuum Plants
2000 ml	RE 210351/01	RE 210353	RE 210352/01	RE 210354	ASPIRET - ASKI R Series HOSPIVAC Series Central Vacuum Plants
4000 ml	RE 210006	RE 210007	RE 210008	RE 210306	HOSPIVAC Series Vuoto centralizzato
5000 ml	RE 210010	RE 210013	RE 210012	RE 210307	HOSPIVAC Series Central Vacuum Plants

REUSABLE JARS in APEC® 1745 – FOR STEAM STERILIZATION UP TO 143 °C

	Jar with: cover overflow valve o-ring	Jar	Cover with: overflow valve o-ring	O-ring	Suitable for:
1000 ml	RE 210009	RE 210002	RE 210352/02	RE 210354	ASPIRET ASKIR series (all except C30 series) Central Vacuum Plants
2000 ml	RE 210351/05	RE 210353/01	RE 210352/02	RE 210354	ASPIRET - ASKI R Series HOSPIVAC Series Central Vacuum Plants
5000 ml	RE 210010/01	RE 210013/01	RE 210012/01	RE 210307	HOSPIVAC Series Vuoto centralizzato

FLOVAC® DISPOSABLE LINERS equipped with polyethylene disposable liner, hydrophobic filter, antibacterial filter, overflow system, reusable container with clear graduated scale in ml with 50ml intervals. The gelling kit is a powder inside liners with germicidal function turning the sucked liquid into a semisolid mass, preventing cross-contamination risks of staff in charge for hygiene and waste disposal.

FLOVAC® DISPOSABLE LINERS & CONTAINERS

	Liner with: cover filter	Liner with: cover filter gelling kit	Reusable Container	Suitable for
1000 ml	31848	31858	31843**	ASPIRET ASKIR series (all except C30 series)
1000 ml	31845	31854	31840	Central Vacuum Plants
2000 ml	31846	31855	31841	ASPIRET - ASKI R Series HOSPIVAC Series Central Vacuum Plants
3000 ml	31847	31856	31842	HOSPIVAC Series Central Vacuum Plants

** Requires additional round spacer (SP.0220) when ordered for ASKIR Series

Hermetically welded **RIGID LID**

Flovac® Disposable Liner
1000 ml / 2000 ml / 3000 ml

PATIENT PORT for connection of the tube going to the patient

Plug to close the PATIENT port before disposal

VACUUM PORT for connection to the vacuum central plant or to CA-MI suction unit

TANDEM PORT for connection of several liners in cascade

Plug to close the TANDEM port when only one container is in use and/or before final disposal

Flovac® Reusable Container
1000 ml / 2000 ml / 3000 ml

OVERFLOW VALVE
FLOVAC® disposable containers are equipped with a GORE™ Medical Membrane hydrophobic filterwith antibacterial, anti-foaming and electrosurgical smoke protection.

SUPPORT RING
A support ring with a spring clip allows the suction tube to be easily fixed in to avoid obstructions.

The disposable soft LINER is made in polyethylene and is hermetically welded to a rigid lid inside which the hydrophobic, antireflux and antibacterial filter is placed. This filter also operates as overflow valve system deactivating suction whenever maximum fill capacity is reached. The liner has to be placed in its dedicated reusable and autoclavable FLOVAC® rigid CONTAINER in policarbonate. FLOVAC® systems replace therefore the use of autoclavable jars, decreasing the costs for cleaning and sterilization. A full line of accessories make FLOVAC® line the ideal partner for collecting liquids and fluids.

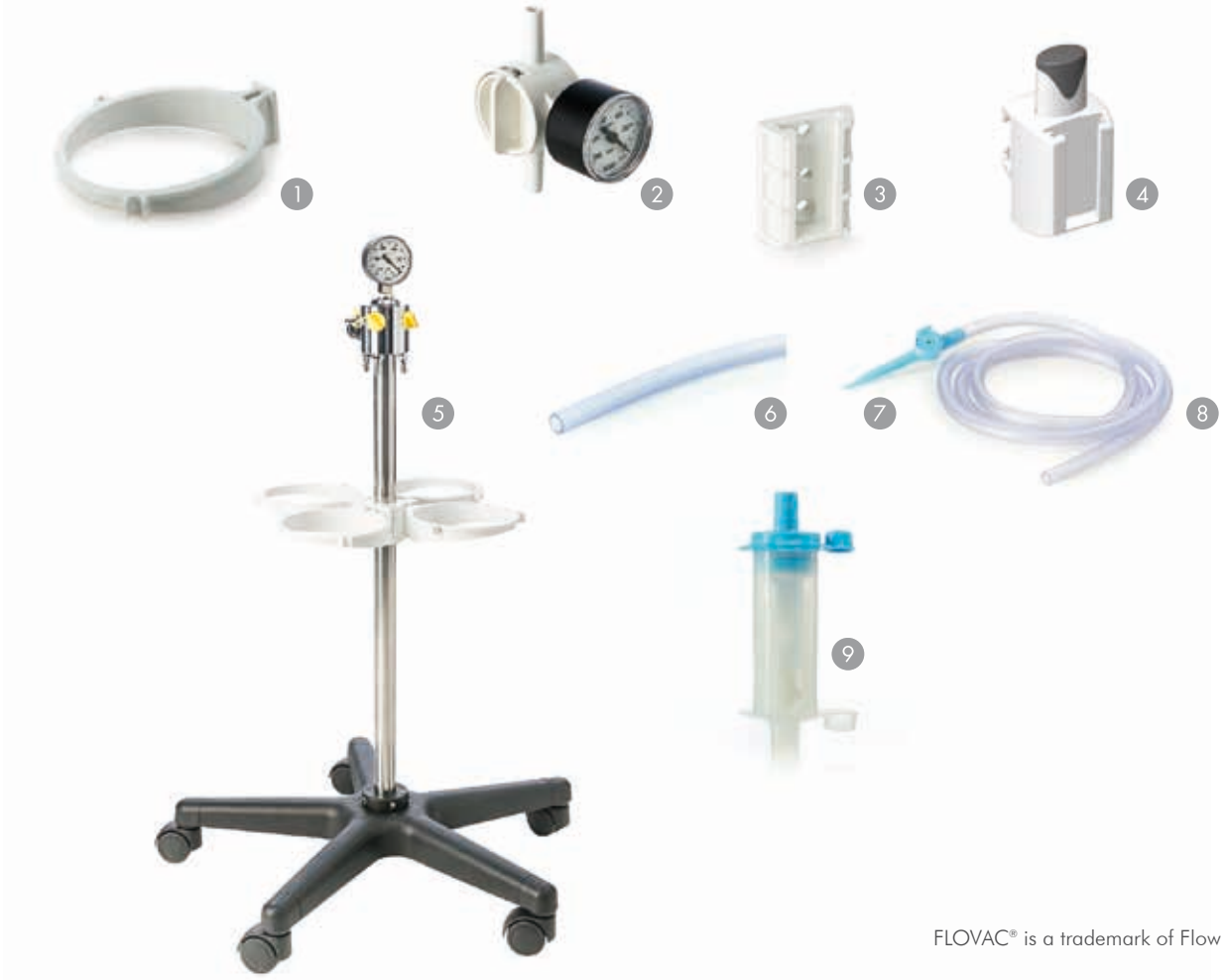
FLOVAC® LINER TECHNICAL FEATURES

Lid material	HDPE (high density polyethylene)
"VACUUM" port	Conic connector, female
"PATIENT" port	Ø 14.0 ÷ 15.5 mm (Ø 8.0 ÷ 9.2 mm with elbow connector)
"TANDEM" port	Ø 8.0 ÷ 9.2 mm
Maximum suction value	-750 mbar (-570 mm Hg)
Maximum graduation interval	50 ml
Patient hose size	Inner Ø ≥ 6 mm L=2.5 m max
Vacuum hose size	Inner Ø ≥ 6 mm L=1.8 m max

FLOVAC® FILTER TECHNICAL FEATURES

Filtration efficiency (typical)	>99.999995% with particle size of 0.1μ
Membrane	100% expanded PTFE GORE™ Medical Membrane
Prefilter	micro fiberglass
Support	non-woven PE/PES

Support ring for FLOVAC® container (all sizes) with 25x5 slide	970010210	1
Support ring for FLOVAC® container (all sizes) with 30x5 slide	970010220	
Support ring for FLOVAC® container (all sizes) with 41x4 slide (also suitable for BAXTER wall slide)	970010214	
Support ring for FLOVAC® container with 45x5 slide (also suitable for ABBOT wall slide)	970010215	
Support ring for autoclavable jars (1000 and 2000 ml) with 25x5 slide	920200422	
ON-OFF tap for mounting on FLOVAC® container support ring	000010057	2
ON-OFF tap with control vacuum gauge for mounting on FLOVAC® container support ring	000010056	
Plastic wall slide 25x5	920200004	3
Plastic wall slide 30x5	920200029	
Plastic wall slide 45x5	920200477	
Metal clamp (chrome-plated) for 30x10 rail with slide 25x5	000230000	4
Plastic clamp (technopolymer) for 30x10 rail with slide 25x5	000230500	
4-place trolley for FLOVAC® container with support ring, ON-OFF tap and control vacuum gauge	000260950	5
4-place trolley for FLOVAC® container with support ring, ON-OFF tap and control vacuum regulator	000260955	
4-place trolley for FLOVAC® with support ring	000260953	
2-place trolley for FLOVAC® container with support ring, ON-OFF tap and control vacuum gauge	000260951	
2-place trolley for FLOVAC® container with support ring, ON-OFF tap and control vacuum regulator	000260956	
2-place trolley for FLOVAC® with support ring	000260954	
Tandem tube Ø 8x11 L=0.38 m for cascade connection	970010120	6
Disposable vacuum breaker	000320000	7
Disposable vacuum breaker with 1.8m hose	000320010	8
Specimen container	000036100	9



SPARE ACCESSORIES

		ASPIRET ASKIR 20 ASKIR 30 ASKIR 230-12V BR ASKIR 30 12V	ASKIR 36 BR ASKIR 36 LI-ION ASKIR 118 ASKIR 118 BASIC	EMIVAC	ASKIR C30 ASKIR C30 BR	HOSPIVAC 350 HOSPIVAC 400 HOSPIVAC BR
	SET of silicone TUBES, FILTERS and CONICAL CONNECTORS					
	Tube Ø 6x10mm Conical connector	RE 210355		RE 210355/01		
	Tube Ø 6x10mm Conical connector Antibacterial filter	SP 0036		SP 0043		
	Tube Ø 8 x 14 mm Conical connector		RE 210355/03		RE 210355/03	RE 210355/03
	Tube Ø 8 x 14 mm Conical connector Antibacterial filter		SP 0036/02		SP 0036/02	SP 0032/01 (for 350 and BR) SP 0032 (for Hospivac 400)
	FLOVAC® liners Tube Ø 6x10mm Conical connector	SP 0158/01				
	FLOVAC® liners Tube Ø 8x14mm Conical connector		SP 0160/01		SP 0160/01	SP 0160/01
	Roll of silicone tube Ø 6x10 mm	Length 1m = SP 0045/02 - Length 10m = SP 0045/03 - Length 50m = SP 0045/04				
	Roll of silicone tube Ø 8X14 mm	Length 1m = SP 0045/05 - Length 10m = SP 0045/06 - Length 50m = SP 0045/07				
	MALE CONNECTORS					
	Ø 8-9-10 mm (pack of 5's)	SP 0223	SP 0223		SP 0223	SP 0223
	CONICAL CONNECTORS					
	Ø 8-9-10 mm	RE 210410		RE 210410		
	Ø 10-11-12 mm		RE 210420		RE 210420	RE 210420
	FILTERS (Antibacterial and Hydrophobic)					
	Ø 64 with 8 mm connector	SP 0046		SP 0046		
	Ø 64 with 11mm connector		SP 0121		SP 0121	SP 0121 (350 and BR only)
	Ø 90 with 11mm connector					SP 0047 (for 400 only)
	ASPIRATION PROBES					
	CH20	RE 210400 (10 pcs)	RE 210400 (10 pcs)		RE 210400 (10 pcs)	
	YANKAUER CANNULAS					
	Yankauer Handle Flat Tip with Hole	2044403	2044403	2044403	2044403	2044403
	Yankauer Handle Crown Tip with Hole	2044401	2044401	2044401	2044401	2044401
	Yankauer Tube L= 180	204413018	204413018	204413018	204413018	204413018
	CATHETER CONTAINER					
	Tube of polycarbonate Ø 54 mm by 400 mm length. Fully autoclavable (121°C - 15 min)					000032
	SILICONE FETAL VACUUM CUPS					
	Length 210 mm, Ø 50 mm, size XS				VC-95100	VC-95100
	Length 210 mm, Ø 60 mm, size S				VC-95200	VC-95200
	Length 210 mm, Ø 70 mm, size M				VC-95300	VC-95300

	ASPIRET ASKIR 20 ASKIR 30 ASKIR 230-12V BR ASKIR 30 12V	ASKIR 36 BR ASKIR 36 LI-ION ASKIR 118 ASKIR 118 BASIC	EMIVAC	ASKIR C30 ASKIR C30 BR	HOSPIVAC 350 HOSPIVAC 400 HOSPIVAC BR
VACUUM GAUGE in mmHg and Kpa					
Ø 40 mm with graduated scale	SP 0018 (for Aspiret)				
Ø 50 mm with graduated scale	SP 0017 (for Askir)	SP 0017 (except ASKIR 118)		SP 0017	
Ø 63 mm with graduated scale					SP 0073
ELECTRONIC BOARD					
for ASKIR 36 LI-ION, ASKIR 118 BASIC		SP 0272			
for ASKIR 230/12V BR, ASKIR 36BR	SP 0205	SP 0205			
for ASKIR C30 - FS version				SP 0107	
for ASKIR C30 BR				SP 0205/01	
for HOSPIVAC – BASIC version					SP 0107/02
for HOSPIVAC – version FS and FULL					SP 0107/03
for HOSPIVAC BR					SP 0271
ON/OFF SWITCH					
Pack of 2's for ASPIRET, ASKIR 20 and 30	SP 0009/04				
Pack of 2's for ASKIR 230/12V BR, 36 BR, C30 BR	SP 0009/08	SP 0009/08		SP 0009/08	
Pack of 1's for ASKIR C30, HOSPIVAC – BASIC				SP 0009/07	SP 0009/07
BATTERY PACK					
Lead type for ASKIR 230/12V BR, 36 BR, C30 BR	SP 0012/01	SP 0012/01		SP 0012/01	
Li-ion type for ASKIR 36 LI-ION, 118, 118 BASIC		SP 0012/03			
Lead type for HOSPIVAC BR					SP 0012/04
WALL MOUNT					
 For ambulance, with recharge and operation function (12V 4A)		ASU 118 (118-WM only)			
Wall mount for support	27736 (except Aspiret and Twin)	27736 (36 models only)			
FOOT-SWITCH CONTROL					
 Footswitch intermittent or continuous operation				SP 0068/01 (FS version)	SP 0068/01 (FS and FULL)
STAND on CASTORS					
 Stand on 5 castors with brakes (antistatic upon request)	27731 (for ASPIRET)	27730 (36BR and LI-ION)		SP 0213	SP 0113/01 (BASIC version)
Base on 4 antistatic castors only for HOSPIVAC	27730 (for ASKIR serie)				SP 0113/03 (FS and FULL)
POWER ADAPTER					
Car adapter 12V for ASKIR 30 12V	SP 0021/01	SP 0007/02 (not for 118 WM)			
Car adapter 12V	SP 0007/02 (for 230 12V BR)				
Power adapter AC/DC	SP 0208/01 (for 230 12V BR)	SP 0208/01		SP 0208/01 (for C30 BR)	
Power cord	SP 0020/03 (for 230 12V BR)	SP 0020/03		SP 0020/03 (for C30 BR)	
CARRY BAG					
 for any model with 1000 ml jar	SP 0207/02	SP 0207/02			
for any model with 2000 ml jar	SP 0207	SP 0207			
for ASKIR 118		SP 0207/01			

DESK-TYPE suction units

MODEL	TYPE of JAR / CONFIGURATION	REF- NO.
NEW ASPIRET:	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310001
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310001/01
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 310001/19
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 310001/20
	1000ml Flovac® Disposable Liner	RE 310002
	2000ml Flovac® Disposable Liner	RE 310002/01
NEW ASKIR 20:	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310100/12
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310100/13
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 310100/64
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 310100/70
	1000ml Flovac® Disposable Liner	RE 310101/12
	2000ml Flovac® Disposable Liner	RE 310101/13
NEW ASKIR 30:	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310100/02
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310100/03
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 310100/74
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 310100/63
	1000ml Flovac® Disposable Liner	RE 310101/02
	2000ml Flovac® Disposable Liner	RE 310100/53
NEW ASKIR 30 Proximity:	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310100/02
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310100/03
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 310100/75
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 310100/62
	1000ml Flovac® Disposable Liner	RE 310101/02
	2000ml Flovac® Disposable Liner	RE 310100/53

EMERGENCY suction units

MODEL	TYPE of JAR / CONFIGURATION	REF- NO.
NEW ASKIR 30 12V	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310150/02
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310150/05
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 310150/10
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 310150/11
	1000ml Flovac® Disposable Liner	RE 310150/12
	2000ml Flovac® Disposable Liner	RE 310150/13
NEW EMIVAC	400 ml Autoclavable Jar in Policarbonate	RE 310300

ON CASTORS
suction units

MODEL		TYPE of JAR / CONFIGURATION	REF- NO.
ASKIR C30	BASIC	Double 2000ml Autoclavable Jars in Makrolon® (max 121°C)	RE 410250
	FS	Double 2000ml Makrolon® Jars + Footswitch	RE 410250/01
	BASIC AP	Double 2000ml Autoclavable Jars in Apec® (max 143°C)	RE 410250/16
	FS AP	Double 2000ml Apec® Jars + Footswitch	RE 410250/15
	BASIC FLOVAC	Double 2000ml Flovac® Disposable Liners	RE 410250/10
	FS FLOVAC	Double 2000ml Flovac® Liners + Footswitch	RE 410250/14
NEW HOSPIVAC 350	BASIC 2	Double 2000ml Autoclavable Jars in Makrolon® (max 121°C)	RE 410356
	FS 2	Double 2000ml Makrolon® Jars + Footswitch	RE 410356/06
	FULL 2	Double 2000ml Makrolon® Jars + Footswitch + Change-Over	RE 410356/01
	BASIC 5	Double 5000ml Autoclavable Jars in Makrolon® (max 121°C)	RE 410356/39
	FS 5	Double 5000ml Makrolon® Jars + Footswitch	RE 410356/40
	FULL 5	Double 5000ml Makrolon® Jars + Footswitch + Change-Over	RE 410356/41
	BASIC PSU 2	Double 2000ml Autoclavable Jars in Polysulfone	RE 410356/59
	FS PSU 2	Double 2000ml Polysulfone Jars + Footswitch	RE 410356/60
	FULL PSU 2	Double 2000ml Polysulfone Jars + Footswitch + Change-Over	RE 410356/61
	BASIC PSU 5	Double 5000ml Autoclavable Jars in Polysulfone	RE 410356/62
	FS PSU 5	Double 5000ml Polysulfone Jars + Footswitch	RE 410356/63
	FULL PSU 5	Double 5000ml Polysulfone Jars + Footswitch + Change-Over	RE 410356/64
	BASIC AP 2	Double 2000ml Autoclavable Jars in Apec® (max 121°C)	RE 410356/56
	FS AP 2	Double 2000ml Apec® Jars + Footswitch	RE 410356/38
	FULL AP 2	Double 2000ml Apec® Jars + Footswitch + Change-Over	RE 410356/55
	BASIC AP 5	Double 5000ml Autoclavable Jars in Apec® (max 121°C)	RE 410356/58
	FS AP 5	Double 5000ml Apec® Jars + Footswitch	RE 410356/54
	FULL AP 5	Double 5000ml Apec® Jars + Footswitch + Change-Over	RE 410356/43
	BASIC FLOVAC 2	Double 2000ml Flovac® Liners	RE 410356/27
	FS FLOVAC 2	Double 2000ml Flovac® Liners + Footswitch	RE 410356/29
	FULL FLOVAC 2	Double 2000ml Flovac® Liners + Footswitch + Change-Over	RE 410356/28
	BASIC FLOVAC 3	Double 3000ml Flovac® Liners	RE 410356/02
	FS FLOVAC 3	Double 3000ml Flovac® Liners + Footswitch	RE 410356/09
	FULL FLOVAC 3	Double 3000ml Flovac® Liners + Footswitch + Change-Over	RE 410356/30
NEW HOSPIVAC 400	BASIC 2	Double 2000ml Autoclavable Jars in Makrolon® (max 121°C)	RE 410350
	FS 2	Double 2000ml Makrolon® Jars + Footswitch	RE 410350/09
	FULL 2	Double 2000ml Makrolon® Jars + Footswitch + Change-Over	RE 410350/01
	BASIC 5	Double 5000ml Autoclavable Jars in Makrolon® (max 121°C)	RE 410350/36
	FS 5	Double 5000ml Makrolon® Jars + Footswitch	RE 410350/37
	FULL 5	Double 5000ml Makrolon® Jars + Footswitch + Change-Over	RE 410350/38
	BASIC PSU 2	Double 2000ml Autoclavable Jars in Polysulfone	RE 410350/57
	FS PSU 2	Double 2000ml Polysulfone Jars + Footswitch	RE 410350/58
	FULL PSU 2	Double 2000ml Polysulfone Jars + Footswitch + Change-Over	RE 410350/59
	BASIC PSU 5	Double 5000ml Autoclavable Jars in Polysulfone	RE 410350/60
	FS PSU 5	Double 5000ml Polysulfone Jars + Footswitch	RE 410350/61
	FULL PSU 5	Double 5000ml Polysulfone Jars + Footswitch + Change-Over	RE.410350/62
	BASIC AP 2	Double 2000ml Autoclavable Jars in Apec® (max 121°C)	RE 410350/40
	FS AP 2	Double 2000ml Apec® Jars + Footswitch	RE 410350/46
	FULL AP 2	Double 2000ml Apec® Jars + Footswitch + Change-Over	RE 410350/33
	BASIC AP 5	Double 5000ml Autoclavable Jars in Apec® (max 121°C)	RE 410350/48
	FS AP 5	Double 5000ml Apec® Jars + Footswitch	RE 410350/39
	FULL AP 5	Double 5000ml Apec® Jars + Footswitch + Change-Over	RE 410350/47
	BASIC FLOVAC 2	Double 2000ml Flovac® Liners	RE 410350/08
	FS FLOVAC 2	Double 2000ml Flovac® Liners + Footswitch	RE 410350/03
	FULL FLOVAC 2	Double 2000ml Flovac® Liners + Footswitch + Change-Over	RE 410350/11
	BASIC FLOVAC 3	Double 3000ml Flovac® Liners	RE 410350/27
	FS FLOVAC 3	Double 3000ml Flovac® Liners + Footswitch	RE 410350/28
	FULL FLOVAC 3	Double 3000ml Flovac® Liners + Footswitch + Change-Over	RE 410350/25

DESK-TYPE BATTERY OPERATED suction units

MODEL	TYPE of JAR / CONFIGURATION	REF- NO.
NEW ASKIR 118	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410151
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 410151/05
	1000ml Flovac® Disposable Liner	RE 410151/02
NEW ASKIR 118-WM	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410150
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 410150/05
	1000ml Flovac® Disposable Liner	RE 410150/02
NEW ASKIR 118 BASIC	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410171
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 410171/03
	1000ml Flovac® Disposable Liner	RE 410171/01
NEW ASKIR 118 BASIC-WM	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410170
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 410170/03
	1000ml Flovac® Disposable Liner	RE 410170/01
NEW ASKIR 230/12V BR	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310211
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 310211/01
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 310211/06
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 310211/11
	1000ml Flovac® Disposable Liner	RE 310211/03
	2000ml Flovac® Disposable Liner	RE 310211/04
ASKIR 36BR (LEAD)	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410200/03
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410200/09
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 410200/10
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 410200/12
	1000ml Flovac® Disposable Liner	RE 410201
	2000ml Flovac® Disposable Liner	RE 410201/01
ASKIR 36BR (LI-ION)	1000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410205
	2000ml Autoclavable Jar in Makrolon® (max 121°C)	RE 410205/01
	1000ml Autoclavable Jar in Apec® (max 143°C)	RE 410205/04
	2000ml Autoclavable Jar in Apec® (max 143°C)	RE 410205/05
	1000ml Flovac® Disposable Liner	RE 410205/02
	2000ml Flovac® Disposable Liner	RE 410205/03

ON CASTORS BATTERY OPERATED suction units

MODEL		TYPE of JAR / CONFIGURATION	REF- NO.
ASKIR C30 BR	BASIC	Double 2000ml Autoclavable Jars in Makrolon® (max 121°C)	RE 410251
	BASIC AP	Double 2000ml Autoclavable Jars in Apec® (max 143°C)	RE 410251/03
	BASIC FLOVAC	Double 2000ml Flovac® Disposable Liners	RE 410251/01
NEW HOSPIVAC BR	FULL 2	Double 2000ml Makrolon® Jars + Footswitch + Change-Over	RE 410400
	FULL 5	Double 5000ml Makrolon® Jars + Footswitch + Change-Over	RE 410400/03
	FULL FLOVAC 2	Double 2000ml Flovac® Liners + Footswitch + Change-Over	RE 410400/01
	FULL FLOVAC 3	Double 3000ml Flovac® Liners + Footswitch + Change-Over	RE 410400/02

CA·MI

Italian Medical Touch

SURGICAL SUCTION UNITS

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CM005.REV6 WEB EDITION 02-2021

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	CA-MI S.r.l.
Manufacturer address and contact details	Via Ugo La Malfa 13 – Frazione Pilastro 43013 Langhirano (PR) Italy e-mail: m.saccani@ca-mi.it
Single Registration Number (SRN) (if available)	IT-MF-000020076

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	TÜV SÜD PRODUCT SERVICE GMBH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024
End date of extended validity/transition period	31/12/2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

CA-MI srl
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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☒ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:	CA-MI S.r.l.
Location & Date:	Langhirano (PR) Italy, 04.04.2024
Signature, Print Name, Title	Manuel Saccani (Quality Assurance / Person Responsible for Regulatory Compliance)

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Contact Details (at least email)	m.saccani@ca-mi.it / tecnico@ca-mi.it

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Italian Medical Touch

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
COMPACT (REF RE 300200)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Aerosol Therapy Equipment Budi: 805461091OZ121590023V	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
COMPACT (REF RE 300200/02)						
MINIMAX (REF RE 300250)						
ZEFIRO (REF RE 300250/03)						
SIMPLE (REF RE 300250/04)						
MINIMAX 2 (REF RE 300250/05)						
MINIMAX (REF RE 300250/06)						
MINIMAX COMBY (REF RE 300250/08)						
SEA FAIR (REF RE 300250/11)						
GEM (REF RE 300250/10)						
PRONTEX FLOW (REF RE 300230)						
FARMASOL (REF RE 300230/01)						
ME 100 (REF RE 300230/02)						
EVERCHECK NB200 (REF RE 300240/03)						
KUBYNEB (REF RE 300240)						
KUBYNEB (REF RE 300240/01)						
EVERCHECK NB100 (REF RE 300240/02)						
AEROPLUS (REF RE 300240/03)						
ME 110 (REF RE 300240/04)						
EOLO (REF RE 300400)						
EOLO (REF RE 300400/05)						
FLO-EOLO (REF RE 300400/15)						
EOLO (REF RE 300400/07)						
EOLO (REF RE 300400/12)						
EOLO (REF RE 300400/16)						

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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PRONTEX WIND (REF RE 300430)						
EVOLUTION (REF RE 300450)						
MOBILE (REF RE 300700)						
MOBILE (REF RE 300700/04)						
CLINEB (REF RE 300550/03)						
CLINEB BASIC (REF RE 300551/03)						
AIR THERAPY (REF RE 300550/02)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Aerosol Therapy Equipment Budi: 805461091OZ121590023V	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
CLINEB PRO (REF RE 300560)						
MIKO (REF RE 300600/03)						
MIKO BASIC (REF RE 300600/12)						
BABY MIKO (REF RE 300600/08)						
MIKO (REF RE 300600/11)						
AIR PLUS 2000 (REF RE 300600/15)						
AEROPHARMA (REF RE 300600/17)						
MIKO (REF RE 300600/18)						
KIWI PLUS (REF RE 300911)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Aerosol Therapy Equipment Budi: 805461091OZ12159002MHPF	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ONE PLUS (REF RE 300912)						
ONE PRO (REF RE 300912/01)						
AIREASY ON (REF RE 300912/02)						
HI-FLO KIT (REF RE 300300/09)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Kits For Aerosol Therapy Budi: 8054610910R060101T3	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
HI-FLO KIT (REF RE 300300)						
HI-FLO KIT (REF RE 300300/01)						
HI-FLO KIT (REF RE 300300/02)						
HI-FLO KIT (REF RE 300300/05)						
HI-FLO KIT (REF RE 300300/06)						
HI-FLO KIT (REF RE 300300/12)						
SET ACCESSORI AEROSOLTERAPIA (REF RE 300300/13)						
HI-FLO KIT (REF RE 300300/15)						
PRONTEX AMPOLLA AEROSOL RAPID 2 (REF 01200)						

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
HI-4 KIT (REF RE 300350) HI-4 + BOCCHERUOLA (REF RE 300350/01)						
NASO-FREE (REF DN 100100) RHINO CARE (REF DN 100100/02) NASO-FREE (REF DN 100100/03)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Kits For Aerosol Therapy Budi: 8054610910R06992S	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW VAPINAL (REF RE 420000) INALFAST (REF RE 420000/01) NEW VAPINAL (REF RE 320000) TERMALVAP (REF RE 320000/03) INALPHARMA (REF RE 320000/10)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Thermal Water Inhaler Budi: 80546109102121590002IPT	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASPIRET (REF RE 310001) NEW ASPIRET (REF RE 310001/01) NEW ASPIRET (REF RE 310002) NEW ASPIRET (REF RE 310002/01) NEW ASPIRET (REF RE 310001/07) NEW ASPIRET (REF RE 310001/13) NEW ASKIR 15 (REF RE 310001/15) NEW ASKIR 15 (REF RE 310001/16) NEW ASKIR 15 (REF RE 310001/17) NEW ASKIR 15 (REF RE 310001/18) KATASPIR 20 ECO (REF RE 310001/06) LIFEMED 15 (REF RE 310001/14) NEW ASPIRET (REF RE 310001/19)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 8054610910Z1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 20 (REF RE 310100/12) NEW ASKIR 20 (REF RE 310100/13) NEW ASKIR 20 (REF RE 310100/64) NEW ASKIR 20 (REF RE 310100/70) NEW ASKIR 20 (REF RE 310101/12) NEW ASKIR 20 (REF RE 310101/13) KATASPIR 20 (REF RE 310100/46)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 8054610910Z1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable

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LIFEMED 20 (REF RE 310100/58)						
NEW ASKIR (REF RE 310100/72)						
TECNO 15 (REF RE 310100/66)						
TECNO 15 (REF RE 310100/67)						
NEW ASKIR 30 (REF RE 310100/02)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 8054610910Z1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 30 (REF RE 310100/03)						
NEW ASKIR 30 (REF RE 310101/02)						
NEW ASKIR 30 (REF RE 310100/53)						
NEW ASKIR 30 (REF RE 310100/18)						
NEW ASKIR 30 (REF RE 310100/30)						
NEW ASKIR 30 (REF RE 310100/40)						
NEW ASKIR 30 (REF RE 310100/63)						
NEW ASKIR 30 (REF RE 310100/74)						
NEW ASKIR (REF RE 310100/71)						
KATASPIR 30 (REF RE 310100/21)						
LIFEMED 40 (REF RE 310100/57)						
TECNO 25 (REF RE 310100/68)						
TECNO 25 (REF RE 310100/69)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/55)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 8054610910Z1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 30 PROXIMITY (REF RE 310100/56)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/62)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/75)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/76)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/77)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/78)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/79)						

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NEW ASKIR 30 PROXIMITY (REF RE 310101/03)						
NEW ASKIR 30 PROXIMITY (REF RE 310101/04)						
NEW ASKIR 30 PROXIMITY (REF RE 310101/07)						
NEW ASKIR 30 PROXIMITY (REF RE 310101/089						
AS-100 (REF RE 410100)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461091OZ1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
AS-100 (REF RE 410100/04)						
ASPIMED 2.3 (REF RE 410100/26)						
ACEEVAC SUC 81025 (REF RE 410100/01)						
AS-200 (REF RE 410120)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461091OZ1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
AS-200 (REF RE 4101120/01)						
ASPIMED 2.2 (REF RE 410120/25)						
NEW ASKIR 230/12V BR (REF RE 310211)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461091OZ1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 230/12V BR (REF RE 310211/01)						
NEW ASKIR 230/12V BR (REF RE 310211/03)						
NEW ASKIR 230/12V BR (REF RE 310211/04)						
NEW ASKIR 230/12V BR (REF RE 310211/06)						
NEW ASKIR 230/12V BR (REF RE 310211/11)						
NEW ASKIR 230/12V BR (REF RE 310211/12)						
NEW ASKIR 230/12V BR (REF RE 310211/13)						
NEW ASKIR 230/12V BR (REF RE 310211/14)						
NEW ASKIR 230/12V BR (REF RE 310211/15)						
NEW ASKIR 230/12V BR (REF RE 310211/10)						
KATASPIR 230/12V BR (REF RE 310211/02)						
TECNO 16B (111-A) (REF RE 310211/08)						
TECNO 16B (114-A) (REF RE 310211/09)						
AS-12VBR (REF RE 410200)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ASPIMED 2.5 (REF RE 410200/02)						

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	Budi: 805461091OZ1120105WL					
ASKIR 36BR (REF RE 410200/03)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461091OZ1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ASKIR 36BR (REF RE 410200/09)						
ASKIR 36BR (REF RE 410200/12)						
ASKIR 36BR (REF RE 410200/13)						
ASKIR 36BR (REF RE 410200/14)						
ASKIR 36BR (REF RE 410200/10)						
ASKIR 36BR (REF RE 410201)						
ASKIR 36BR (REF RE 410201/01)						
ASKIR 36BR (REF RE 410200/04)						
NEW ASKIR 36BR (REF RE 410200/05)						
NEW ASKIR 36BR (REF RE 410200/06)						
NEW ASKIR (REF RE 410200/11)						
KATASPIR 36BR (REF RE 410200/07)						
AS-36BR (REF RE 410210/01)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461091OZ1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
AS-36BR (REF RE 410210/03)						
AS-36BR (REF RE 410210/04)						
CEEVAC SUC 81030 (REF RE 410210/02)						
NEW ASKIR 36 LI-ION (REF RE 410205)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461091OZ1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 36 LI-ION (REF RE 410205/01)						
NEW ASKIR 36 LI-ION (REF RE 410205/02)						
NEW ASKIR 36 LI-ION (REF RE 410205/03)						
NEW ASKIR 36 LI-ION (REF RE 410205/04)						
NEW ASKIR 36 LI-ION (REF RE 410205/05)						
NEW ASKIR 36 LI-ION (REF RE 410205/06)						
NEW ASKIR 36 LI-ION (REF RE 410205/07)						
NEW ASKIR 36 LI-ION (REF RE 410205/08)						
NEW ASKIR 36 LI-ION (REF RE 410205/09)						
NEW ASKIR 36 LI-ION (REF RE 410205/10)						
NEW ASKIR 36 LI-ION (REF RE 410205/11)						

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NEW ASKIR 118 (REF RE 410150)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 8054610910Z1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 118 (REF RE 410150/01)						
NEW ASKIR 118 (REF RE 410150/02)						
NEW ASKIR 118 (REF RE 410150/05)						
NEW ASKIR 118 (REF RE 410151)						
NEW ASKIR 118 (REF RE 410151/01)						
NEW ASKIR 118 (REF RE 410150/02)						
NEW ASKIR 118 (REF RE 410151/05)						
NEW ASKIR 30 12V (REF RE 310150/02)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 8054610910Z1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 30 12V (REF RE 310150/05)						
NEW ASKIR 118 BASIC (REF RE 410171)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 8054610910Z1120105WL	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 118 BASIC (REF RE 410171/01)						
NEW ASKIR 118 BASIC (REF RE 410171/02)						
NEW ASKIR 118 BASIC (REF RE 410171/03)						
NEW ASKIR 118 BASIC (REF RE 410171/04)						
NEW ASKIR 118 BASIC (REF RE 410171/05)						
NEW ASKIR 118 BASIC (REF RE 410171/06)						
NEW ASKIR 118 BASIC (REF RE 410171/07)						
NEW ASKIR 118 BASIC (REF RE 410170)						
NEW ASKIR 118 BASIC (REF RE 410170/01)						
NEW ASKIR 118 BASIC (REF RE 410170/02)						
NEW ASKIR 118 BASIC (REF RE 410170/03)						
ASKIR C30 (REF RE 410250)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ASKIR C30 (REF RE 410250/01)						
ASKIR C30 (REF RE 410250/10)						
ASKIR C30 (REF RE 410250/14)						
ASKIR C30 (REF RE 410250/15)						
ASKIR C30 (REF RE 410250/16)						
ASKIR C30 BR	MDD 93/42/EEC Certificate	26.05.2024	TÜV SÜD	TÜV SÜD	31.12.2028	Not Applicable

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
(REF RE 410251)	No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP		PRODUCT SERVICE GMBH (0123)	PRODUCT SERVICE GMBH (0123)		
ASKIR C30 BR (REF RE 410251/01)						
ASKIR C30 BR (REF RE 410251/03)						
ASKIR C30 BR (REF RE 410251/04)						
ASKIR C30 BR (REF RE 410251/05)						
ASKIR C30 BR (REF RE 410251/06)						
NEW HOSPIVAC BR (REF RE 410400)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW HOSPIVAC BR (REF RE 410400/01)						
NEW HOSPIVAC BR (REF RE 410400/02)						
NEW HOSPIVAC BR (REF RE 410400/03)						
NEW HOSPIVAC 400 (REF RE 410350)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW HOSPIVAC 400 (REF RE 410350/01)						
NEW HOSPIVAC 400 (REF RE 410350/03)						
NEW HOSPIVAC 400 (REF RE 410350/05)						
NEW HOSPIVAC 400 (REF RE 410350/08)						
NEW HOSPIVAC 400 (REF RE 410350/09)						
NEW HOSPIVAC 400 (REF RE 410350/10)						
NEW HOSPIVAC 400 (REF RE 410350/11)						
NEW HOSPIVAC 400 (REF RE 410350/18)						
NEW HOSPIVAC 400 (REF RE 410350/25)						
NEW HOSPIVAC 400 (REF RE 410350/27)						
NEW HOSPIVAC 400 (REF RE 410350/28)						
NEW HOSPIVAC 400 (REF RE 410350/36)						
NEW HOSPIVAC 400 (REF RE 410350/37)						
NEW HOSPIVAC 400 (REF RE 410350/38)						
NEW HOSPIVAC 400 (REF RE 410350/39)						
NEW HOSPIVAC 400 (REF RE 410350/30)						
NEW HOSPIVAC 400 (REF RE 410350/32)						
NEW HOSPIVAC 400 (REF RE 410350/33)						
NEW HOSPIVAC 400 (REF RE 410350/35)						
NEW HOSPIVAC 400						

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
(REF RE 410350/40)						
NEW HOSPIVAC 400 (REF RE 410350/43)						
NEW HOSPIVAC 400 (REF RE 410350/44)						
NEW HOSPIVAC 400 (REF RE 410350/45)						
NEW HOSPIVAC 400 (REF RE 410350/46)						
NEW HOSPIVAC 400 (REF RE 410350/47)						
NEW HOSPIVAC 400 (REF RE 410350/48)						
NEW HOSPIVAC 400 (REF RE 410350/57)						
NEW HOSPIVAC 400 (REF RE 410350/58)						
NEW HOSPIVAC 400 (REF RE 410350/59)						
NEW HOSPIVAC 400 (REF RE 410350/60)						
NEW HOSPIVAC 400 (REF RE 410350/61)						
NEW HOSPIVAC 400 (REF RE 410350/62)						
NEW HOSPIVAC 400 (REF RE 410350/65)						
NEW HOSPIVAC 400 (REF RE 410350/66)						
NEW HOSPIVAC 400 (REF RE 410350/67)						
NEW HOSPIVAC 400 (REF RE 410350/62)						
NEW HOSPIVAC 400 (REF RE 410350/68)						
NEW HOSPIVAC 400 (REF RE 410350/69)						
NEW HOSPIVAC 400 (REF RE 410350/70)						
NEW HOSPIVAC 400 (REF RE 410350/71)						
NEW HOSPIVAC 400 (REF RE 410350/72)						
LIFEMED 90 (REF RE 410350/13)						
KYRI DSS (REF RE 410350/41)						
TECNO 90 (REF RE 410350/55)						
TECNO 90 (REF RE 410350/56)						
TECNO 90 (REF RE 410350/49)						
KATASPIR PRO (REF RE 410350/50)						
KATASPIR PRO (REF RE 410350/51)						
HiFlo2 – SUC 84602 (REF RE 410350/63)						
HiFlo2 Max						

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
SUC 84604 (REF RE 410350/64)						
NEW HOSPIVAC 350 (REF RE 410356)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW HOSPIVAC 350 (REF RE 410356/01)						
NEW HOSPIVAC 350 (REF RE 410356/02)						
NEW HOSPIVAC 350 (REF RE 410356/05)						
NEW HOSPIVAC 350 (REF RE 410356/06)						
NEW HOSPIVAC 350 (REF RE 410356/07)						
NEW HOSPIVAC 350 (REF RE 410356/08)						
NEW HOSPIVAC 350 (REF RE 410356/09)						
NEW HOSPIVAC 350 (REF RE 410356/27)						
NEW HOSPIVAC 350 (REF RE 410356/28)						
NEW HOSPIVAC 350 (REF RE 410356/29)						
NEW HOSPIVAC 350 (REF RE 410356/30)						
NEW HOSPIVAC 350 (REF RE 410356/39)						
NEW HOSPIVAC 350 (REF RE 410356/40)						
NEW HOSPIVAC 350 (REF RE 410356/41)						
NEW HOSPIVAC 350 (REF RE 410356/38)						
NEW HOSPIVAC 350 (REF RE 410356/43)						
NEW HOSPIVAC 350 (REF RE 410356/54)						
NEW HOSPIVAC 350 (REF RE 410356/55)						
NEW HOSPIVAC 350 (REF RE 410356/56)						
NEW HOSPIVAC 350 (REF RE 410356/58)						
TECNO 40 (REF RE 410356/57)						
NEW HOSPIVAC 350 (REF RE 410350/25)						
NEW HOSPIVAC 350 (REF RE 410350/26)						
NEW HOSPIVAC 350 (REF RE 410350/32)						
NEW HOSPIVAC 350 (REF RE 410350/36)						
NEW HOSPIVAC 350 (REF RE 410350/37)						
NEW HOSPIVAC 350 (REF RE 410350/34)						
NEW HOSPIVAC 350 (REF RE 410350/51)						

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
NEW HOSPIVAC 350 (REF RE 410350/52)						
NEW HOSPIVAC 350 (REF RE 410350/53)						
NEW HOSPIVAC 350 (REF RE 410350/44)						
NEW HOSPIVAC 350 (REF RE 410350/46)						
NEW HOSPIVAC 350 (REF RE 410350/47)						
NEW HOSPIVAC 350 (REF RE 410350/48)						
NEW HOSPIVAC 350 (REF RE 410350/49)						
NEW HOSPIVAC 350 (REF RE 410350/50)						
NEW HOSPIVAC 350 (REF RE 410350/51)						
NEW HOSPIVAC 350 (REF RE 410350/52)						
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NEW HOSPIVAC 350 (REF RE 410350/59)						
NEW HOSPIVAC 350 (REF RE 410350/60)						
NEW HOSPIVAC 350 (REF RE 410350/61)						
NEW HOSPIVAC 350 (REF RE 410350/62)						
NEW HOSPIVAC 350 (REF RE 410350/63)						
NEW HOSPIVAC 350 (REF RE 410350/64)						
NEW HOSPIVAC 350 (REF RE 410350/65)						
NEW HOSPIVAC 350 (REF RE 410350/66)						
NEW HOSPIVAC 350 (REF RE 410350/67)						
NEW HOSPIVAC 350 (REF RE 410350/68)						
NEW HOSPIVAC 350 (REF RE 410350/69)						
NEW HOSPIVAC 350 (REF RE 410350/70)						
NEW HOSPIVAC 350 (REF RE 410350/71)						
NEW HOSPIVAC 350 (REF RE 410350/72)						
NEW EMIVAC (REF RE 310300)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105MXH	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW MAMILAT (REF DC 620010)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE	TÜV SÜD PRODUCT SERVICE GMBH	31.12.2028	Not Applicable
NEW MAMILAT						

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
(REF DC 620010/02)	Families: Breast Pump Budi: 80546191OZ12030303		GMBH (0123)	(0123)		
SET ACCESSORI TIRALATTE ELETTRICO (REF DC 520016)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Kit for Electric Breast Pump Budi: 805461910Z120803994A	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
CLIAMED TERMOMETRO ASCELLARE (REF TR 200050)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Electronic Thermometer Budi: 805461910V03010102V9	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
digiT-40 (REF TR 200030)						
digiT-40 (REF TR 200030/01)						
digiT-40F (REF TR 200040)						
digiT-40F (REF TR 200040/01)						
digiT-10P (REF TR 200300)						
TERMO FLASH CLENNY (REF TR 200300/01)						
T-Digit (REF TR 200300/02)						

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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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Via Ugo La Malfa, 13
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43013 LANGHIRANO (PR)
ITALY

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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TÜV SÜD Product Service GmbH
Confirmation Letter
CL 063105 0053 Rev. 00

Reference: ITA1816546_CL | 713264114

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: **IT-MF-000020076**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CL 063105 0053 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

16th May 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 895651
Riccardo Cottone

Riccardo Cottone
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Tunde Junaid
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BUDI: 8054610910R060101T3 **Article Number:** REF RE 300300; REF RE 300300/09; REF RE 300300/01; REF RE 300300/02; REF RE 300300/05; REF RE 300300/06; REF RE 300300/12; REF RE 300300/13; REF RE 300300/15; REF 01200; REF RE 300350; REF RE 300350/01	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 8054610910Z120105WL **Article Number:** REF RE 310001; REF RE 310001/01; REF RE 310001/14; REF RE 310001/06; REF RE 310001/19; REF RE 310002; REF RE 310002/01; REF RE 310001/07; REF RE 310001/13; REF RE 310001/15; REF RE 310001/16; REF RE 310001/17; REF RE 310001/18; REF RE 310100/02; REF RE 310100/03; REF RE 310100/18; REF RE 310100/21; REF RE 310100/30; REF RE 310100/40; REF RE 310100/53; REF RE 310100/55; REF RE 310100/56; REF RE 310100/57; REF RE 310100/62; REF RE 310100/63; REF RE 310100/68; REF RE 310100/69; REF RE 310100/71; REF RE 310100/74; REF RE 310100/75; REF RE 310100/76; REF RE 310100/77; REF RE 310100/78; REF RE 310100/79; REF RE 310101/02; REF RE 310101/03; REF RE 310101/04; REF RE 310101/07; REF RE 310101/08; REF RE	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
310100/12; REF RE 310100/13; REF RE 310100/46; REF RE 310100/58; REF RE 310100/64; REF RE 310100/66; REF RE 310100/67; REF RE 310100/72; REF RE 310100/70; REF RE 310101/12; REF RE 310101/13; REF RE 410100; REF RE 410100/01; REF RE 410100/04; REF RE 410100/26; REF RE 410120; REF RE 410120/01; REF RE 410120/25; REF RE 310211; REF RE 310211/01; REF RE 310211/02; REF RE 310211/03; REF RE 310211/04; REF RE 310211/06; REF RE 310211/08; REF RE 310211/09; REF RE 310211/10; REF RE 310211/11; REF RE 310211/12; REF RE 310211/13; REF RE 310211/14; REF RE 310211/15; REF RE 410220; REF RE 410220/02; REF RE 410200/03; REF RE 410200/09; REF RE 410200/13; REF RE 410200/14; REF RE 410200/05; REF RE 410200/06; REF RE 410200/07; REF RE 410200/10; REF RE 410200/11; REF RE 410200/12; REF RE 410201; REF RE 410201/01; REF RE 410201/04; REF RE 410201/05; REF RE 410210/01; REF RE 410210/02; REF RE 410210/03; REF RE 410210/04; REF RE 410205; REF RE 410205/01; REF RE 410205/02; REF RE 410205/03; REF RE 410205/04; REF RE 410205/05; REF RE 410205/06; REF RE 410205/07; REF RE 410205/08; REF RE 410205/09; REF RE 410205/10; REF RE 410205/11; REF RE 410150; REF RE 410150/01; REF RE 410150/02; REF RE 410150/05; REF RE 410151; REF RE 410151/01; REF RE 410151/02; REF RE 410151/05; REF RE 410170; REF RE 410170/01; REF RE 410170/02;			

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REF RE 410170/03; REF RE 410171; REF RE 410171/01; REF RE 410171/02; REF RE 410171/03; REF RE 410171/04; REF RE 410171/06; REF RE 410171/05; REF RE 410171/07; REF RE 310150/02; REF RE 310150/05;			
BUDI: 805461910R06992S **Article Number:** **REF DN 100100; REF DN 100100/02; REF DN 100100/03**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: **805461910V03010102V9** **Article Number:** REF TR 200050/01; REF TR 200030; REF TR 200030/01; REF TR 200040; REF TR 200040/01; REF TR 200300; REF TR 200300/01; REF TR 200300/02	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: **805461910Z120105MXH** **Article Number:** REF RE 310300	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
BUDI: 805461910Z120105PXP **Article Number:** REF RE 410250; REF RE 410250/01; REF RE 410250/10; REF RE 410250/14; REF RE 410250/15; REF RE 410250/16; REF RE 410251; REF RE 410251/01; REF RE 410251/03; REF RE 410251/04; REF RE 410251/05; REF RE 410251/06; REF RE 410400; REF RE 410400/01; REF RE 410400/02; REF RE 410400/03; REF RE 410350; REF RE 410350/01; REF RE 410350/09; REF RE 410350/36; REF RE 410350/37; REF RE 410350/38; REF RE 410350/05; REF RE 410350/10; REF RE 410350/18; REF RE 410350/08; REF RE 410350/03; REF RE 410350/11; REF RE 410350/27; REF RE 410350/28; REF RE 410350/25; REF RE 410350/40; REF RE 410350/33; REF RE 410350/46; REF RE 410350/48; REF RE 410350/39; REF RE 410350/47; REF RE 410350/13; REF RE 410350/41; REF RE 410350/49; REF RE 410350/55; REF RE 410350/56; REF RE 410350/50; REF RE 410350/51; REF RE 410350/63; REF RE 410350/64; REF RE 410350/57; REF RE 410350/58; REF RE 410350/59; REF RE 410350/60; REF RE 410350/61; REF RE 410350/62; REF RE 410350/35; REF RE 410350/30; REF RE 410350/32; REF RE 410350/43; REF RE 410350/44; REF RE	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
410350/45; REF RE 410350/65; REF RE 410350/66; REF RE 410350/67; REF RE 410350/68; REF RE 410350/69; REF RE 410350/70; REF RE 410350/71; REF RE 410350/72; REF RE 410356; REF RE 410356/06; REF RE 410356/01; REF RE 410356/39; REF RE 410356/40; REF RE 410356/41; REF RE 410356/05; REF RE 410356/07; REF RE 410356/08; REF RE 410356/27; REF RE 410356/29; REF RE 410356/28; REF RE 410356/02; REF RE 410356/09; REF RE 410356/30; REF RE 410356/56; REF RE 410356/38; REF RE 410356/55; REF RE 410356/58; REF RE 410356/54; REF RE 410356/43; REF RE 410356/57; REF RE 410356/25; REF RE 410356/26; REF RE 410356/32; REF RE 410356/34; REF RE 410356/36; REF RE 410356/37; REF RE 410356/44; REF RE 410356/46; REF RE 410356/47; REF RE 410356/48; REF RE 410356/49; REF RE 410356/50; REF RE 410356/51; REF RE 410356/52; REF RE 410356/53; REF RE 410356/59; REF RE 410356/60; REF RE 410356/61; REF RE 410356/62; REF RE 410356/63; REF RE 410356/64; REF RE 410356/65; REF RE 410356/66; REF RE 410356/67; REF RE 410356/68; REF RE 410356/69; REF RE 410356/70; REF RE 410356/71; REF RE 410356/72;			
BUDI: 805461910Z1208030303 **Article Number:** REF DC 620010; REF DC 620010/02	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
BUDI: 805461910Z120803994A **Article Number:** REF DC 520016	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 805461910Z121590023V **Article Number:** REF RE 300200; REF RE 300200/02; REF RE 300230; REF RE 300230/01; REF RE 300240; REF RE 300240/01; REF RE 300250; REF RE 300250/03; REF RE 300250/04; REF RE 300250/05; REF RE 300250/06; REF RE 300250/08; REF RE 300250/11; REF RE 300400; REF RE 300400/15; REF RE 300400/05; REF RE 300430; REF RE 300450; REF RE 300550/03; REF RE 300551/03; REF RE 300550/02; REF RE 300560; REF RE 300600/03; REF RE 300600/12; REF RE 300600/15; REF RE 300600/17; REF RE 300600/18; REF RE 300700; REF RE 300700/04; REF RE 300400/07; REF RE 300400/12; REF RE 300400/16; REF RE 300600/08; REF RE 300600/11; REF RE 300230/02; REF RE 300240/03; REF RE 300240/02; REF RE 300240/04; REF RE 300250/10; REF RE 300230/03;	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BUDI: **805461910Z12159002IPT** **Article Number:** REF RE 420000; REF RE 420000/01; REF RE 320000; REF RE 320000/03; REF RE 320000/10	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 805461910Z12159002MHPF **Article Number:** REF RE 300911; REF RE 300912; REF RE 300912/01; REF RE 300912/02; REF RE 300912/03	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2 063105 0047 REV. 01 NB#: 0123
BUDI: 805461910V03010199WJ **Article Number:** REF TR 100200; REF TR 100300; REF TR 100200/01; REF TR 100302; REF TR 100303; REF TR 100304; REF TR 100305; REF TR 100307; REF TR 100306	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☒ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2M 063105 0048 REV.00 NB#: 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable			

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/05/16	ITA1816546_CL | 713264114	Initial issue

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	CA-MI S.r.l.
Manufacturer address and contact details	Via Ugo La Malfa 13 – Frazione Pilastro 43013 Langhirano (PR) Italy e-mail: m.saccani@ca-mi.it
Single Registration Number (SRN) (if available)	IT-MF-000020076

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	TÜV SÜD PRODUCT SERVICE GMBH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	MDD 93/42/EEC Certificate No. G2M 063105 0048 Rev.00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024
End date of extended validity/transition period	31/12/2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☒ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:	CA-MI S.r.l.
Location & Date:	Langhirano (PR) Italy, 10.04.2024
Signature, Print Name, Title	Manuel Saccani (Quality Assurance / Person Responsible for Regulatory Compliance)

CA-MI S.r.l.
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Contact Details (at least email)	m.saccani@ca-mi.it / tecnico@ca-mi.it

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
T-CLASSIC (REF TR 100200)	MDD 93/42/EEC Certificate No. G2M 063105 0048 Rev.00 Families: Mercury Free Clinical Thermometer Budi: 8054610910V03010199WJ	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
T-VEDO (REF TR 100200/01)						
T-FLAP (REF TR 100300)						
TERMOMETRO CROWN (REF TR 100302)						
T-FLAP (REF TR 100303)						
KLASYK (REF TR 100304)						
T-GLASS (REF TR 100305)						
TERMO GREEN CLENNY (REF TR 100306)						
PRIMATHERM CLASSIC (REF TR 100307)						

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 063105 0045 Rev. 03

Holder of Certificate: **CA-MI S.R.L.**

CA-MI

Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Certification Mark:

Scope of Certificate:

Design and development, production, service and sale of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers and medical devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 063105 0045 Rev. 03

Report No.: ITA1885389

Valid from: 2022-08-02
Valid until: 2025-08-01

Date, 2022-08-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 063105 0045 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALY

Design and development, production, service and sale of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler) and related accessories, medical devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers and medical devices for phlebology (graduated compression medical stockings). Distribution of active and non-active non implantable medical devices.

CA-MI S.r.l.
Via Strada per Parma 34, Frazione Pilastro, 43013 Langhirano (PR), ITALY

Warehouse of active and non-active non implantable medical devices and components used in production.

CA-MI S.r.l.
Via Ugo La Malfa 27, Frazione Pilastro, 43013 Langhirano (PR), ITALY

Production of medical devices for surgery (electrical and manual suction pumps), warehouse of active and non-active non implantable medical devices and components used in production.

/

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